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(54) **DEVICE FOR SUTURE ATTACHMENT FOR MINIMALLY INVASIVE HEART VALVE REPAIR**

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See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

2,751,908	A	6/1956	Wallace
3,664,330	A	5/1972	Deutsch

(Continued)

FOREIGN PATENT DOCUMENTS

EP	1039851	B1	7/2005
EP	1637091	A2	3/2006

(Continued)

OTHER PUBLICATIONS

PCT International Search Report and Written Opinion, PCT/US2019/050210, dated Dec. 2, 2019, 5 pages.

(Continued)

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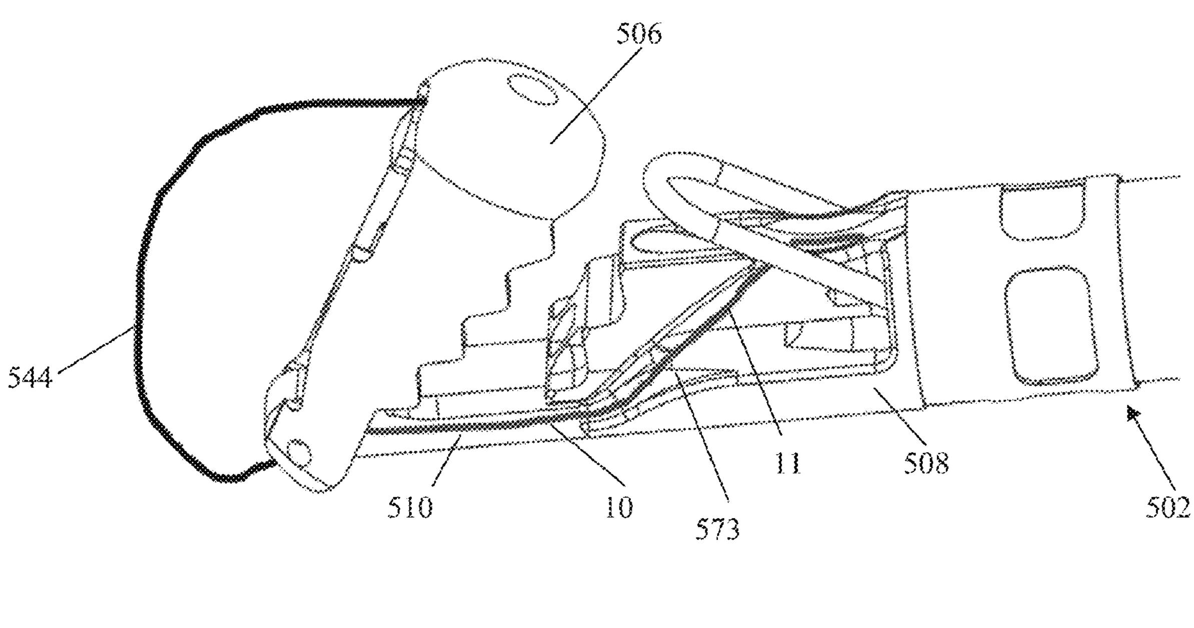
(57) **ABSTRACT**

Disclosed herein are minimally invasive systems and methods for intravascularly accessing the heart and performing a transcatheter repair of a heart valve by inserting a suture as an artificial chordae into a heart valve leaflet. In various embodiments, such systems and methods can be employed in other heart valve repair procedures such an edge to edge repair to coapt leaflets by inserting one or more sutures that retain the leaflets in a coapted positioned or inserting a suture to repair a tear in a leaflet, for example.

20 Claims, 24 Drawing Sheets



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(56) **References Cited**

U.S. PATENT DOCUMENTS

3,667,474 A 6/1972 Lapkin
3,842,840 A 10/1974 Schweizer
4,258,716 A 3/1981 Sutherland
4,351,345 A 9/1982 Carney
4,759,348 A 7/1988 Cawood
4,836,204 A 6/1989 Landymore et al.
4,935,027 A 6/1990 Yoon
4,957,498 A 9/1990 Caspari
4,967,498 A 9/1990 Caspari
4,960,424 A 10/1990 Grooters
4,967,798 A 11/1990 Hammer
4,972,874 A 11/1990 Jackson
5,053,013 A 10/1991 Ensminger
5,059,201 A 10/1991 Asnis
5,211,650 A 5/1993 Noda
5,297,536 A 3/1994 Wilk
5,304,185 A 4/1994 Taylor
5,312,423 A * 5/1994 Rosenbluth A61B 17/12013 606/139
5,336,229 A 8/1994 Noda
5,383,877 A 1/1995 Clarke
5,431,666 A 7/1995 Sauer et al.
5,452,733 A 9/1995 Sterman
5,474,519 A 12/1995 Bloomer
5,547,455 A 8/1996 McKenna et al.
5,556,411 A 9/1996 Taoda et al.
5,571,215 A 11/1996 Sterman
5,601,578 A 2/1997 Murphy
5,626,607 A 5/1997 Malecki
5,653,716 A 8/1997 Malo et al.
5,665,100 A 9/1997 Yoon
5,667,472 A 9/1997 Finn et al.
5,667,473 A 9/1997 Finn et al.
5,667,478 A 9/1997 McFarlin et al.
5,693,091 A 12/1997 Larson, Jr. et al.
5,728,113 A 3/1998 Sherts
5,762,458 A 6/1998 Wang et al.
5,762,613 A 6/1998 Sutton et al.
5,766,163 A 6/1998 Mueller et al.
5,769,791 A 6/1998 Benaron et al.
5,772,597 A 6/1998 Goldberger et al.
5,772,672 A 6/1998 Toy et al.
5,785,658 A 7/1998 Benaron et al.
5,797,960 A 8/1998 Stevens et al.
5,830,231 A 11/1998 Geiges, Jr.
5,839,639 A 11/1998 Sauer et al.
5,857,961 A 1/1999 Vanden Hoek et al.
5,897,564 A 4/1999 Schulze et al.
5,908,428 A 6/1999 Scirica et al.
5,908,429 A 6/1999 Yoon
5,919,128 A 7/1999 Fitch
5,961,440 A 10/1999 Schweich, Jr.
5,972,004 A 10/1999 Williamson et al.
5,972,030 A 10/1999 Garrison et al.
5,984,939 A 11/1999 Yoon
5,993,466 A 11/1999 Yoon
5,993,467 A 11/1999 Yoon
6,022,360 A 2/2000 Reimels et al.
6,045,497 A 4/2000 Schweich, Jr.
6,050,936 A 4/2000 Schweich, Jr.
6,053,933 A 4/2000 Balazs et al.
6,059,715 A 5/2000 Schweich, Jr.
6,077,214 A 6/2000 Mortier et al.
6,117,144 A 9/2000 Nobles et al.
6,129,683 A 10/2000 Sutton et al.
6,149,660 A 11/2000 Laufer et al.
6,152,934 A 11/2000 Harper et al.
6,162,168 A 12/2000 Schweich, Jr.
6,162,233 A 12/2000 Williamson
6,165,119 A 12/2000 Schweich, Jr.
6,165,120 A 12/2000 Schweich, Jr.
6,165,183 A 12/2000 Kuehn et al.
6,178,346 B1 1/2001 Amundson et al.
6,179,195 B1 1/2001 Adams et al.
6,183,411 B1 2/2001 Mortier et al.
6,190,357 B1 2/2001 Ferrari et al.
6,234,079 B1 5/2001 Chertkow
6,234,995 B1 5/2001 Peacock, III
6,245,079 B1 6/2001 Nobles et al.
6,260,552 B1 7/2001 Mortier et al.
6,261,222 B1 7/2001 Schweich, Jr.
6,264,602 B1 7/2001 Mortier et al.
6,269,819 B1 8/2001 Oz et al.
6,270,508 B1 8/2001 Klleman et al.
6,283,993 B1 9/2001 Cosgrove et al.
6,312,447 B1 11/2001 Grimes
6,332,863 B1 12/2001 Schweich, Jr. et al.
6,332,864 B1 12/2001 Schweich, Jr. et al.
6,332,893 B1 12/2001 Mortier et al.
6,355,050 B1 3/2002 Andreas et al.
6,401,720 B1 6/2002 Stevens et al.
6,402,679 B1 6/2002 Mortier et al.
6,402,680 B2 6/2002 Mortier et al.
6,402,781 B1 6/2002 Langberg et al.
6,406,420 B1 6/2002 McCarthy et al.
6,419,626 B1 7/2002 Yoon
6,436,107 B1 8/2002 Wang et al.
6,443,922 B1 9/2002 Roberts et al.
6,451,054 B1 9/2002 Stevens
6,461,366 B1 10/2002 Seguin
6,508,777 B1 1/2003 Macoviak et al.
6,514,194 B2 2/2003 Schweich, Jr. et al.
6,533,796 B1 3/2003 Sauer et al.
6,537,198 B1 3/2003 Vidlund et al.
6,537,314 B2 3/2003 Langberg et al.
6,551,331 B2 4/2003 Nobles et al.
6,558,416 B2 5/2003 Cosgrove et al.
6,562,052 B2 5/2003 Nobles et al.
6,564,805 B2 5/2003 Garrison et al.
6,582,388 B1 6/2003 Coleman et al.
6,585,727 B1 7/2003 Cashman et al.
6,589,160 B2 7/2003 Schweich, Jr. et al.
6,602,288 B1 8/2003 Cosgrove et al.
6,616,684 B1 9/2003 Vidlund et al.
6,619,291 B2 9/2003 Hlavka et al.
6,622,730 B2 9/2003 Ekvall et al.
6,626,917 B1 9/2003 Craig
6,626,930 B1 9/2003 Allen et al.
6,629,534 B1 10/2003 St. Goar et al.
6,629,921 B1 10/2003 Schweich, Jr. et al.
6,629,984 B1 10/2003 Chan
6,645,205 B2 11/2003 Ginn
6,679,268 B2 1/2004 Stevens et al.
6,692,605 B2 2/2004 Kerr et al.
6,695,866 B1 2/2004 Kuehn et al.
6,709,456 B2 3/2004 Langberg et al.
6,718,985 B2 4/2004 Hlavka et al.
6,723,038 B1 4/2004 Schroeder et al.
6,733,509 B2 5/2004 Nobles et al.
6,740,107 B2 5/2004 Loeb et al.
6,743,239 B1 6/2004 Kuehn et al.
6,746,471 B2 6/2004 Mortier et al.
6,752,713 B2 6/2004 Johnson, Jr.
6,752,813 B2 6/2004 Goldfarb et al.
6,755,777 B2 6/2004 Schweich, Jr. et al.
6,764,510 B2 7/2004 Vidlund et al.
6,770,083 B2 8/2004 Seguin
6,770,084 B1 8/2004 Bain et al.
6,793,618 B2 9/2004 Schweich, Jr. et al.
6,802,860 B2 10/2004 Cosgrove et al.
6,808,488 B2 10/2004 Mortier et al.
6,810,882 B2 11/2004 Langberg et al.
6,840,246 B2 1/2005 Downing
6,858,003 B2 2/2005 Evans et al.
6,875,224 B2 4/2005 Grimes
6,893,448 B2 5/2005 O'Quinn et al.

(56) **References Cited**

U.S. PATENT DOCUMENTS

6,896,686 B2 5/2005 Weber
6,908,424 B2 6/2005 Mortier et al.
6,918,917 B1 7/2005 Nguyen et al.
6,921,407 B2 7/2005 Nguyen et al.
6,929,715 B2 8/2005 Fladda et al.
6,936,054 B2 8/2005 Chu
6,955,175 B2 10/2005 Stevens et al.
6,962,605 B2 11/2005 Cosgrove et al.
6,978,176 B2 12/2005 Lattouf
6,986,775 B2 1/2006 Morales et al.
6,989,028 B2 1/2006 Lashinski et al.
6,991,635 B2 1/2006 Takamoto et al.
6,997,950 B2 2/2006 Chawla
7,004,176 B2 2/2006 Lau
7,004,952 B2 2/2006 Nobles et al.
7,011,669 B2 3/2006 Kimblad
7,044,905 B2 5/2006 Vidlund et al.
7,048,754 B2 5/2006 Martin et al.
7,077,862 B2 7/2006 Vidlund et al.
7,083,628 B2 8/2006 Bachman
7,083,638 B2 8/2006 Foerster
7,090,686 B2 8/2006 Nobles et al.
7,094,244 B2 8/2006 Schreck
7,100,614 B2 9/2006 Stevens et al.
7,112,207 B2 9/2006 Allen et al.
7,112,219 B2 9/2006 Vidlund et al.
7,115,110 B2 10/2006 Frazier et al.
7,118,583 B2 10/2006 O'Quinn et al.
7,122,040 B2 10/2006 Hill et al.
7,179,291 B2 2/2007 Rourke et al.
7,186,264 B2 3/2007 Liddicoat et al.
7,189,199 B2 3/2007 McCarthy et al.
7,217,240 B2 5/2007 Snow
7,226,467 B2 6/2007 Lucatero et al.
7,247,134 B2 7/2007 Vidlund et al.
7,250,028 B2 7/2007 Julian et al.
7,288,097 B2 10/2007 Seguin
7,294,148 B2 11/2007 McCarthy
7,381,210 B2 6/2008 Zarbatany et al.
7,464,712 B2 12/2008 Oz et al.
7,563,267 B2 7/2009 Goldfarb et al.
7,563,273 B2 7/2009 Goldfarb et al.
7,604,646 B2 10/2009 Goldfarb et al.
7,608,091 B2 10/2009 Goldfarb et al.
7,635,386 B1 12/2009 Gammie
7,666,204 B2 2/2010 Thornton et al.
7,815,654 B2 10/2010 Chu
7,879,048 B2 2/2011 Bain et al.
7,887,552 B2 2/2011 Bachman
8,465,500 B2 6/2013 Speziali
8,545,551 B2 10/2013 Loulmet
8,758,393 B2 * 6/2014 Zentgraf A61B 17/0469 606/207
8,968,338 B2 3/2015 Speziali
9,044,221 B2 6/2015 Zengraf et al.
9,192,374 B2 11/2015 Zentgraf
9,364,213 B2 6/2016 Speziali
9,572,556 B2 2/2017 Skinlo et al.
9,700,300 B2 7/2017 Speziali
10,582,924 B2 3/2020 Speziali
10,588,620 B2 * 3/2020 Caffes A61B 17/00234
2001/0005787 A1 6/2001 Oz
2001/0016675 A1 8/2001 Mortier et al.
2001/0021872 A1 9/2001 Bailey et al.
2002/0013571 A1 1/2002 Goldfarb et al.
2002/0020732 A1 * 2/2002 Adams A61B 17/072 227/180.1
2002/0029080 A1 3/2002 Mortier et al.
2002/0049402 A1 4/2002 Peacock, III
2002/0077524 A1 6/2002 Schweich, Jr.
2002/0091382 A1 * 7/2002 Hooven A61B 18/14 606/41
2002/0169359 A1 11/2002 McCarthy
2002/0173694 A1 11/2002 Mortier et al.
2002/0183766 A1 12/2002 Seguin
2002/0183787 A1 12/2002 Wahr et al.
2003/0004562 A1 1/2003 DiCarlo
2003/0032979 A1 2/2003 Mortier et al.
2003/0050529 A1 3/2003 Vidlund et al.
2003/0050693 A1 3/2003 Quijano
2003/0078599 A1 4/2003 O'Quinn et al.
2003/0078600 A1 4/2003 O'Quinn et al.
2003/0105519 A1 6/2003 Fasol
2003/0120341 A1 6/2003 Shennib et al.
2003/0130731 A1 7/2003 Vidlund et al.
2003/0163029 A1 8/2003 Sonnenschein et al.
2003/0166992 A1 9/2003 Schweich, Jr.
2003/0167071 A1 9/2003 Martin et al.
2003/0171641 A1 9/2003 Schweich, Jr.
2003/0181928 A1 9/2003 Vidlund et al.
2003/0187457 A1 10/2003 Weber
2003/0195529 A1 10/2003 Takamoto et al.
2003/0199975 A1 10/2003 Gabbay
2004/0003819 A1 1/2004 St. Goar
2004/0030382 A1 2/2004 St. Goar
2004/0039442 A1 2/2004 St. Goar
2004/0044350 A1 3/2004 Martin et al.
2004/0044365 A1 3/2004 Bachman
2004/0049207 A1 3/2004 Goldfarb et al.
2004/0049552 A1 3/2004 Motoyama
2004/0087975 A1 5/2004 Lucatero et al.
2004/0087978 A1 5/2004 Velez et al.
2004/0092962 A1 5/2004 Thornton et al.
2004/0097805 A1 5/2004 Verard et al.
2004/0116767 A1 6/2004 Lebovic
2004/0122448 A1 6/2004 Levine
2004/0127983 A1 7/2004 Mortier et al.
2004/0133063 A1 7/2004 McCarthy et al.
2004/0167374 A1 8/2004 Schweich et al.
2004/0167539 A1 8/2004 Kuehn et al.
2004/0225300 A1 11/2004 Goldfarb et al.
2004/0225304 A1 11/2004 Vidlund et al.
2004/0236353 A1 11/2004 Bain et al.
2004/0236354 A1 11/2004 Seguin
2004/0236373 A1 11/2004 Anspach, III
2004/0243229 A1 12/2004 Vidlund et al.
2004/0267083 A1 12/2004 McCarthy
2005/0004668 A1 1/2005 Aklog et al.
2005/0021055 A1 1/2005 Toubia et al.
2005/0021056 A1 1/2005 St. Goar
2005/0021057 A1 1/2005 St. Goar
2005/0033446 A1 2/2005 Deem et al.
2005/0065396 A1 3/2005 Mortier et al.
2005/0075723 A1 4/2005 Schroeder et al.
2005/0075727 A1 4/2005 Wheatley
2005/0101975 A1 5/2005 Nguyen et al.
2005/0125011 A1 6/2005 Spence et al.
2005/0131277 A1 6/2005 Schweich, Jr.
2005/0131533 A1 6/2005 Alfieri et al.
2005/0143620 A1 6/2005 Mortier et al.
2005/0148815 A1 7/2005 Mortier et al.
2005/0149014 A1 7/2005 Hauck et al.
2005/0154402 A1 7/2005 Sauer et al.
2005/0165419 A1 7/2005 Sauer et al.
2005/0171601 A1 8/2005 Cosgrove
2005/0216039 A1 9/2005 Lederman
2005/0240202 A1 10/2005 Shennib et al.
2005/0251187 A1 11/2005 Beane et al.
2006/0020275 A1 1/2006 Goldfarb et al.
2006/0036317 A1 2/2006 Vidlund et al.
2006/0041306 A1 2/2006 Vidlund et al.
2006/0052868 A1 3/2006 Mortier et al.
2006/0058871 A1 3/2006 Zakay et al.
2006/0074484 A1 4/2006 Huber
2006/0074485 A1 4/2006 Realyvasquez
2006/0089671 A1 4/2006 Goldfarb et al.
2006/0100699 A1 5/2006 Vidlund et al.
2006/0127509 A1 6/2006 Eckman
2006/0135993 A1 6/2006 Seguin
2006/0149123 A1 7/2006 Vidlund et al.
2006/0161040 A1 7/2006 McCarthy
2006/0161193 A1 7/2006 Beane et al.
2006/0184203 A1 8/2006 Martin et al.
2006/0195012 A1 8/2006 Mortier et al.

(56) **References Cited**

U.S. PATENT DOCUMENTS

2006/0195134 A1	8/2006	Crittenden	
2006/0195183 A1	8/2006	Navia et al.	
2006/0241340 A1	10/2006	Vidlund	
2006/0287657 A1	12/2006	Bachman	
2007/0002627 A1	1/2007	Youn	
2007/0027451 A1	2/2007	Desinger et al.	
2007/0049952 A1	3/2007	Weiss	
2007/0050022 A1	3/2007	Vidlund et al.	
2007/0055303 A1	3/2007	Vidlund et al.	
2007/0088375 A1	4/2007	Beane et al.	
2007/0100356 A1	5/2007	Lucatero et al.	
2007/0112244 A1	5/2007	McCarthy	
2007/0118151 A1	5/2007	Davidson	
2007/0118154 A1	5/2007	Crabtree	
2007/0118155 A1	5/2007	Goldfarb et al.	
2007/0118213 A1	5/2007	Loulmet	
2007/0129737 A1	6/2007	Goldfarb et al.	
2007/0179511 A1	8/2007	Paolitto	
2007/0197858 A1	8/2007	Goldfarb et al.	
2007/0203391 A1	8/2007	Bloom et al.	
2007/0232941 A1	10/2007	Rabinovich	
2007/0239272 A1	10/2007	Navia et al.	
2007/0265643 A1	11/2007	Beane et al.	
2007/0299468 A1	12/2007	Viola	
2008/0004485 A1	1/2008	Moreschi	
2008/0027468 A1	1/2008	Fenton	
2008/0051703 A1	2/2008	Thornton et al.	
2008/0065011 A1	3/2008	Marchand et al.	
2008/0065156 A1	3/2008	Hauser et al.	
2008/0065205 A1	3/2008	Nguyen et al.	
2008/0091059 A1	4/2008	Machold	
2008/0091264 A1	4/2008	Machold	
2008/0097482 A1	4/2008	Bain et al.	
2008/0097489 A1	4/2008	Goldfarb et al.	
2008/0109069 A1	5/2008	Coleman et al.	
2008/0125860 A1	5/2008	Webler et al.	
2008/0125861 A1	5/2008	Webler et al.	
2008/0167714 A1	7/2008	St. Goar	
2008/0183194 A1	7/2008	Goldfarb et al.	
2008/0188873 A1	8/2008	Speziali	
2008/0195200 A1	8/2008	Vidlund et al.	
2008/0208006 A1	8/2008	Farr	
2008/0228223 A1	9/2008	Alkhatib	
2008/0243245 A1	10/2008	Thamber et al.	
2009/0062819 A1*	3/2009	Burkhart	A61B 17/0469 606/148
2009/0105729 A1	4/2009	Zentgraf	
2009/0105751 A1	4/2009	Zentgraf	
2009/0131880 A1	5/2009	Speziali et al.	
2009/0156995 A1	6/2009	Martin et al.	
2009/0163934 A1	6/2009	Raschdorf, Jr.	
2009/0192598 A1	7/2009	Lattouf et al.	
2009/0259304 A1	10/2009	O'Beirne et al.	
2010/0030061 A1	2/2010	Canfield et al.	
2010/0042147 A1	2/2010	Janovsky et al.	
2010/0160726 A1	6/2010	Windheuser	
2010/0174297 A1	7/2010	Speziali	
2010/0185172 A1	7/2010	Fabro	
2010/0217283 A1	8/2010	St. Goar	
2010/0298929 A1	11/2010	Thornton et al.	
2011/0011917 A1	1/2011	Loulmet	
2012/0184971 A1	7/2012	Zentgraf et al.	
2013/0035757 A1	2/2013	Zentgraf et al.	
2013/0150710 A1	6/2013	Zentgraf et al.	
2014/0039324 A1	2/2014	Speziali	
2014/0364875 A1	12/2014	Zentgraf	
2015/0148821 A1	5/2015	Speziali	
2017/0290582 A1	10/2017	Speziali	
2019/0290260 A1	9/2019	Caffes et al.	
2019/0343626 A1	11/2019	Smirnov et al.	
2019/0343633 A1	11/2019	Garvin et al.	
2019/0343634 A1	11/2019	Garvin et al.	

FOREIGN PATENT DOCUMENTS

EP	1845861 A2	10/2007
EP	1408850 B1	9/2009
JP	H 04307052 A	10/1992
JP	06142114	5/1994
JP	2004-531337	10/2004
JP	2007-535342	12/2007
WO	WO 1999/000059 A1	1/1999
WO	WO 1999/030647 A1	6/1999
WO	WO 2000/006026 A2	2/2000
WO	WO 2000/006027 A2	2/2000
WO	WO 2000/006028 A1	2/2000
WO	WO 2000/016700 A1	3/2000
WO	WO 2001/066018 A1	9/2001
WO	WO 2001/095809 A1	12/2001
WO	WO 2003/001893 A2	1/2003
WO	WO 2003/059209 A2	7/2003
WO	WO 2003/079937 A2	10/2003
WO	WO 2003/082157 A2	10/2003
WO	WO 2003/082158 A1	10/2003
WO	WO 2004/021893 A1	3/2004
WO	WO 2004/043265 A2	5/2004
WO	WO 2005/039428 A2	5/2005
WO	WO 2005/087140 A1	9/2005
WO	WO 2005/094525 A2	10/2005
WO	WO 2006/012750 A1	2/2006
WO	WO 2006/032051 A2	3/2006
WO	WO 2006/065966 A2	6/2006
WO	WO 2006/078694 A2	7/2006
WO	WO 2006/116310 A2	11/2006
WO	WO 2006/127509 A2	11/2006
WO	WO 2007/002627 A1	1/2007
WO	WO 2007/027451 A2	3/2007
WO	WO 2007/062128 A2	5/2007
WO	WO 2007/081418 A1	7/2007
WO	WO 2007/117612 A1	10/2007
WO	WO 2008/010738 A2	1/2008
WO	WO 2009/052528 A2	4/2009
WO	WO 2011/070477 A1	6/2011
WO	WO 2011/137336 A1	11/2011
WO	WO 2012/167120 A1	12/2012

OTHER PUBLICATIONS

Interactive Cardio Vascular and Thoracic Surgery; Abstracts; Suppl 3 to vol. 7 (Sep. 2008) 52 pages.

Machine translation of JP 06142114.

Port Access System for Mitral Valve Repair Proves Its Value in Study; MedGadget Jul. 9, 2009 (2 pages).

Application and File History for U.S. Appl. No. 12/254,808, filed Oct. 20, 2008, now U.S. Pat. No. 9,192,374. Inventors: Zentgraf.

Application and File History for U.S. Appl. No. 16/678,571, filed Nov. 8, 2019. Inventor: Zentgraf.

Application and File History for U.S. Appl. No. 16/363,701, filed Mar. 25, 2019, now U.S. Pat. No. 10,588,620. Inventors: Caffes et al.

Application and File History for U.S. Appl. No. 16/818,639, filed Mar. 13, 2020. Inventors: Caffes et al.

Application and File History for U.S. Appl. No. 16/406,736 filed May 8, 2019. Inventors: Smirnov et al.

Application and File History for U.S. Appl. No. 16/406,764, filed May 8, 2019. Inventors: Garvin et al.

Application and File History for U.S. Appl. No. 16/406,799, filed May 8, 2019. Inventors: Garvin et al.

Application and File History for U.S. Appl. No. 16/745,074, filed Jan. 16, 2020. Inventors: Edmiston et al.

Application and File History for U.S. Appl. No. 14/947,399, filed Nov. 20, 2015. Inventors: Zeentgraf et al.

* cited by examiner

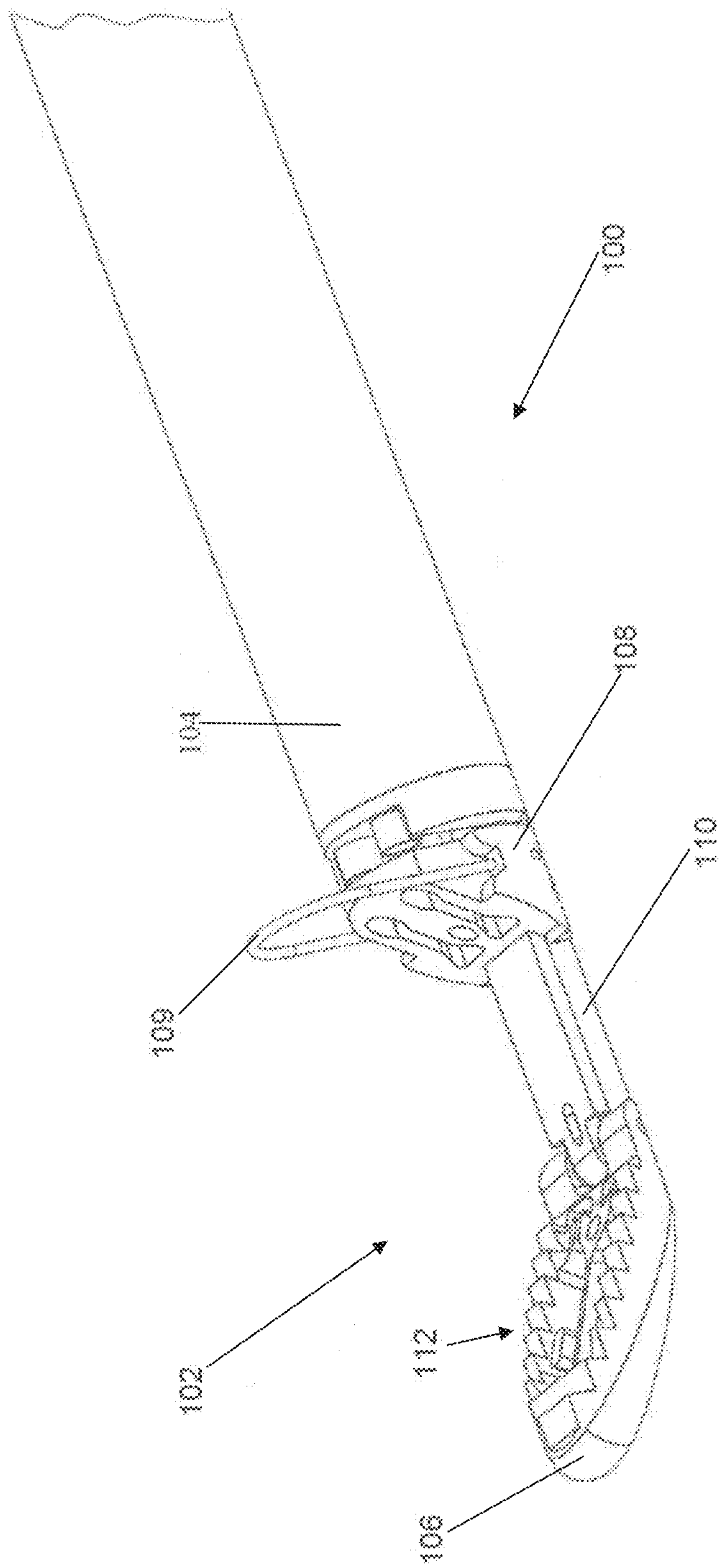


Fig. 1A

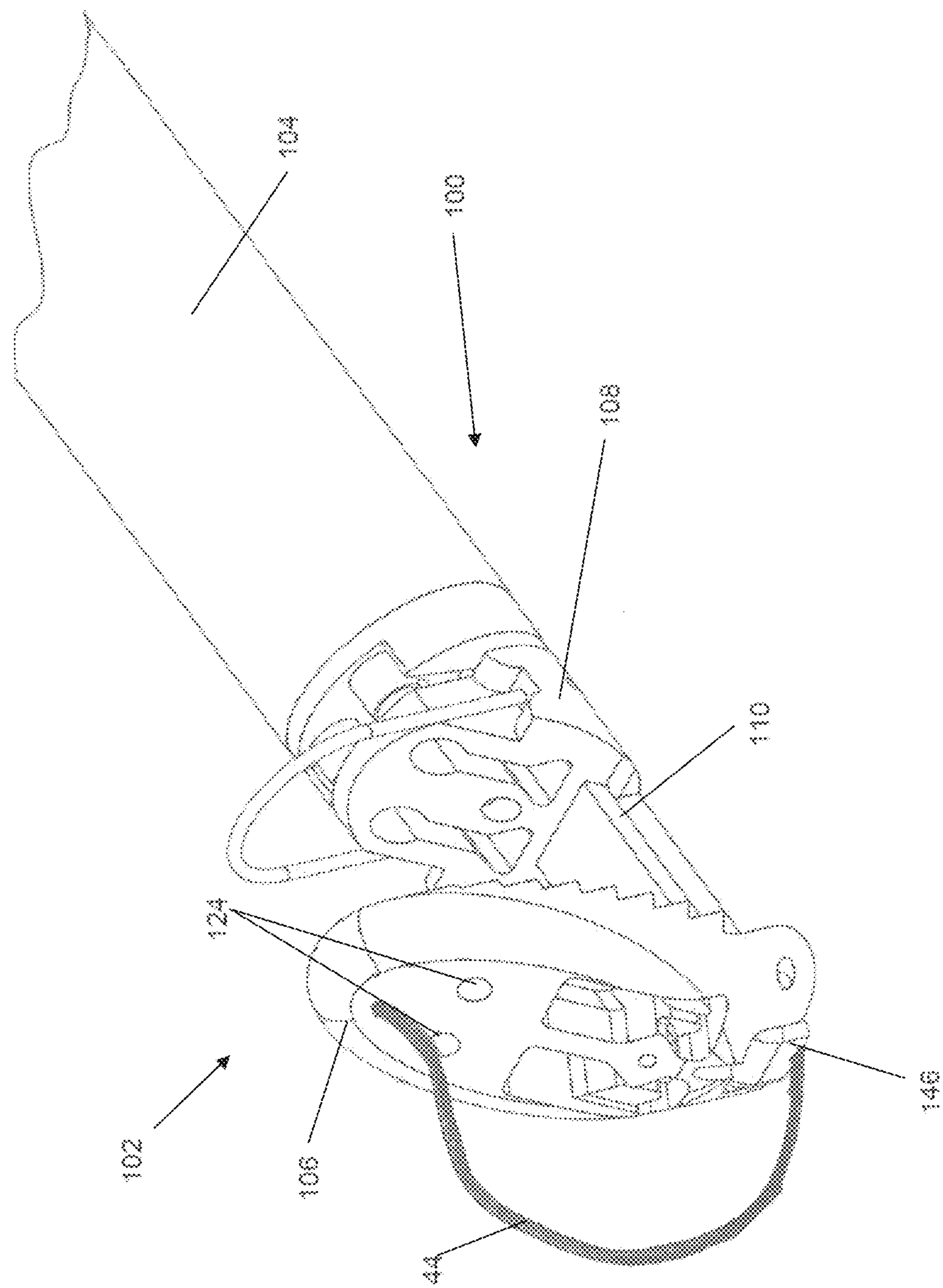


Fig. 1B

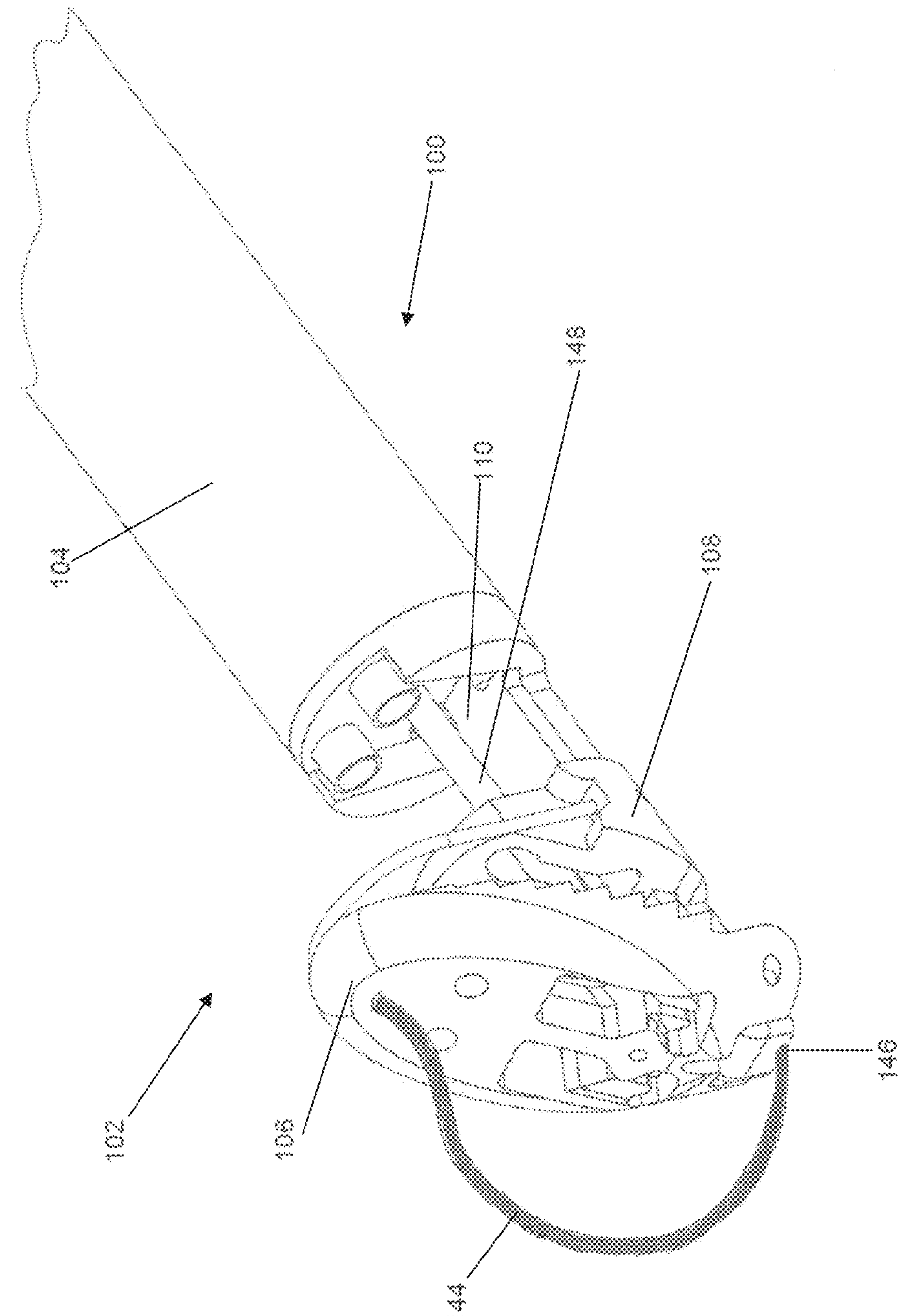
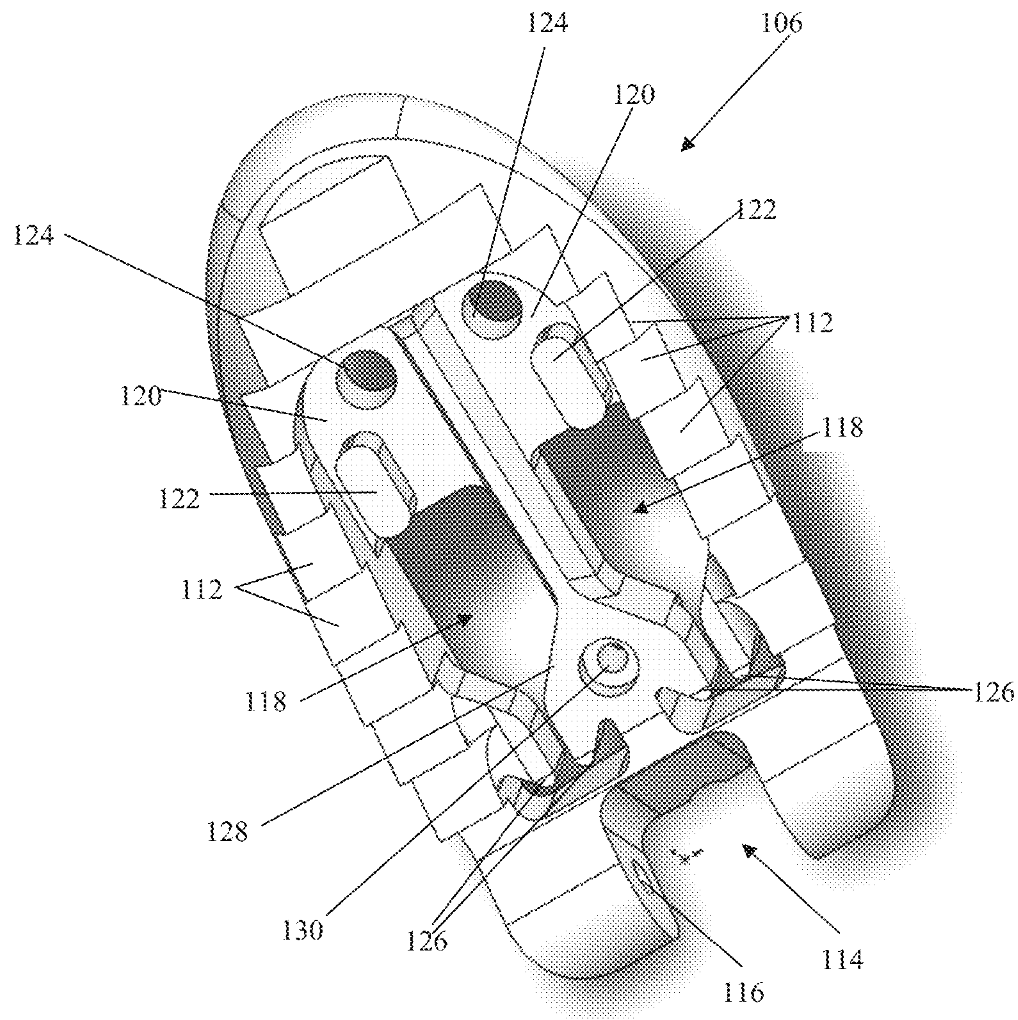


Fig. 1C



124
106
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124
122
112
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118
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118
126
128
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126
116
114

Fig. 2A

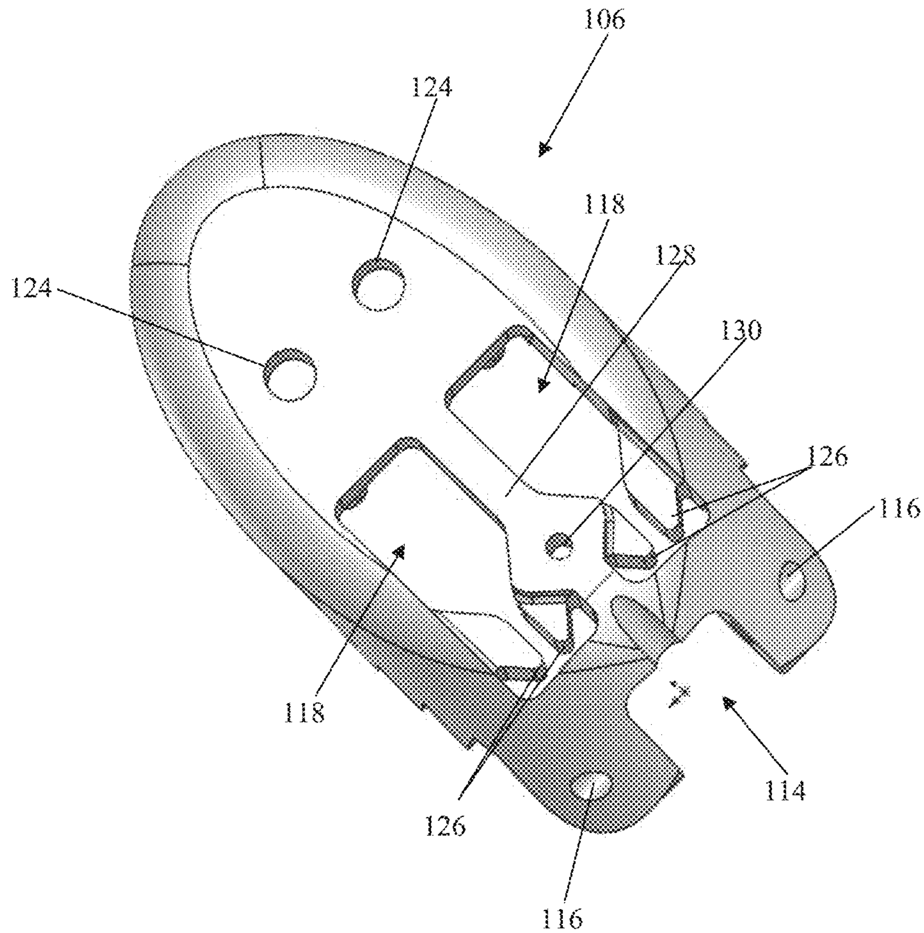


Fig. 2B

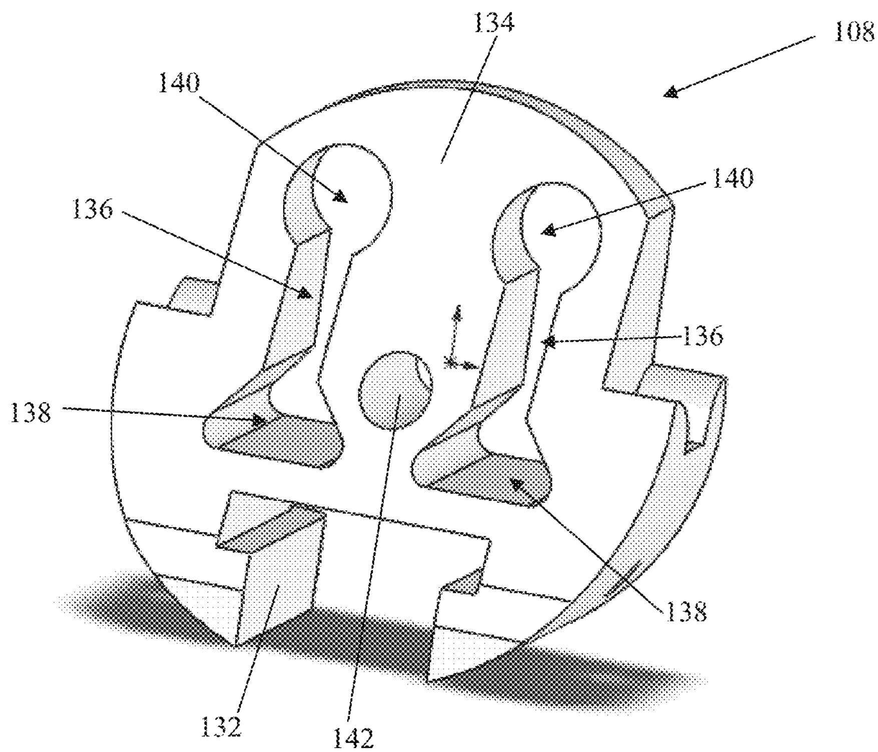


Fig 3

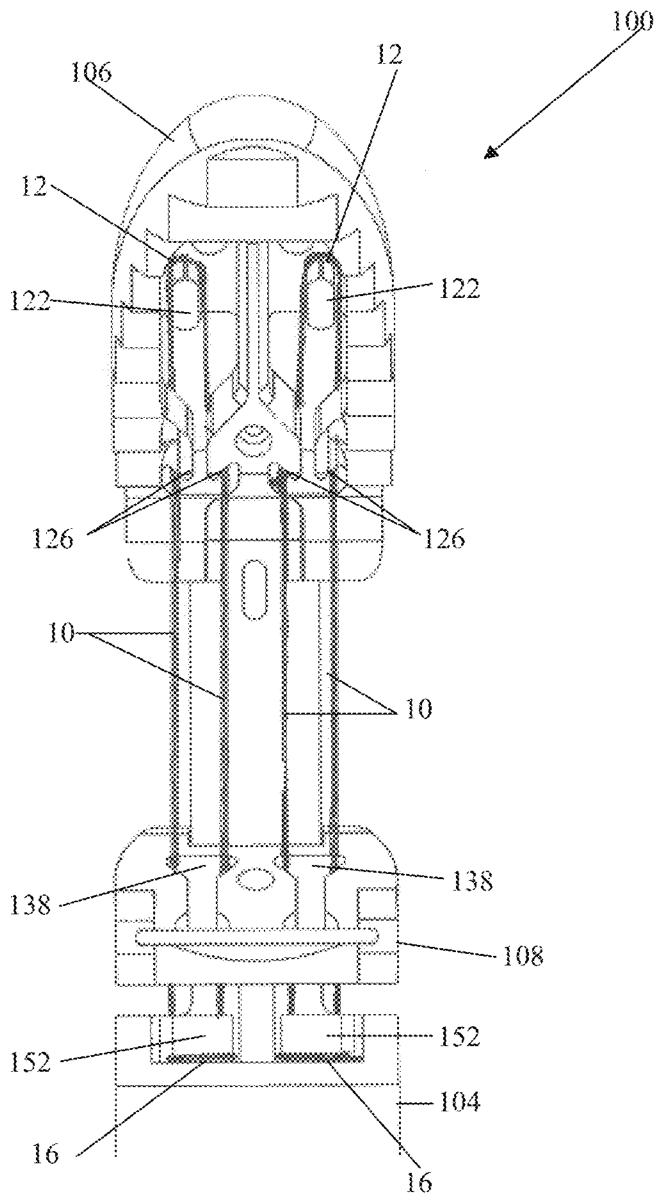


Fig. 4A

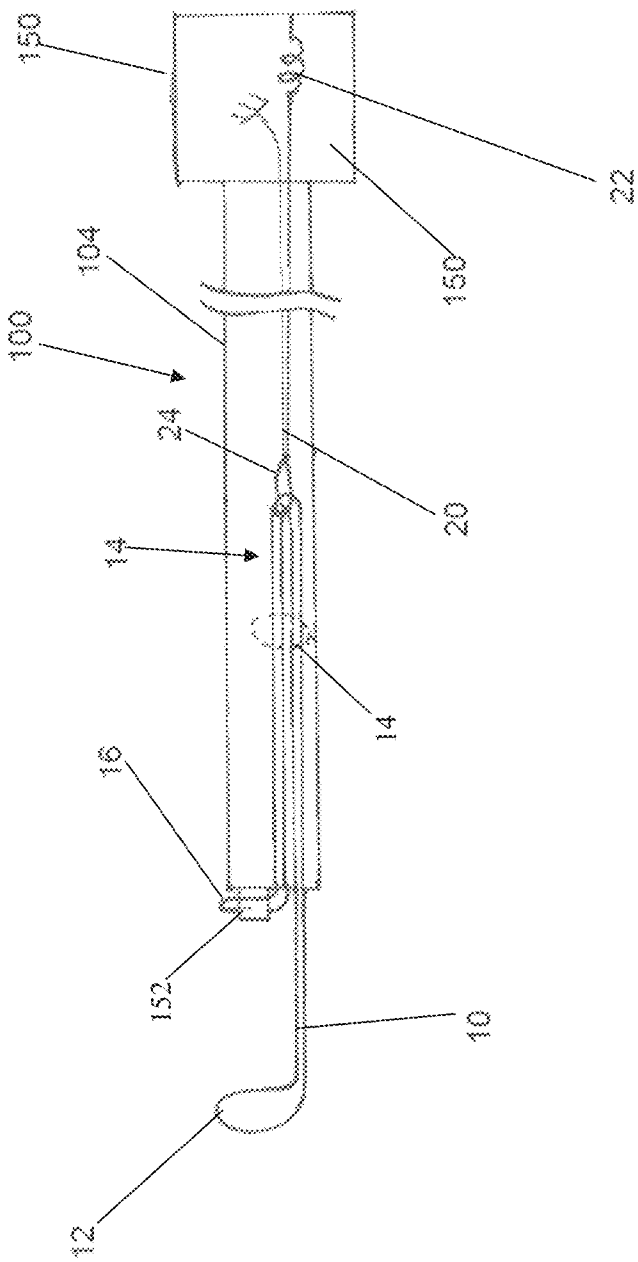


Fig. 4B

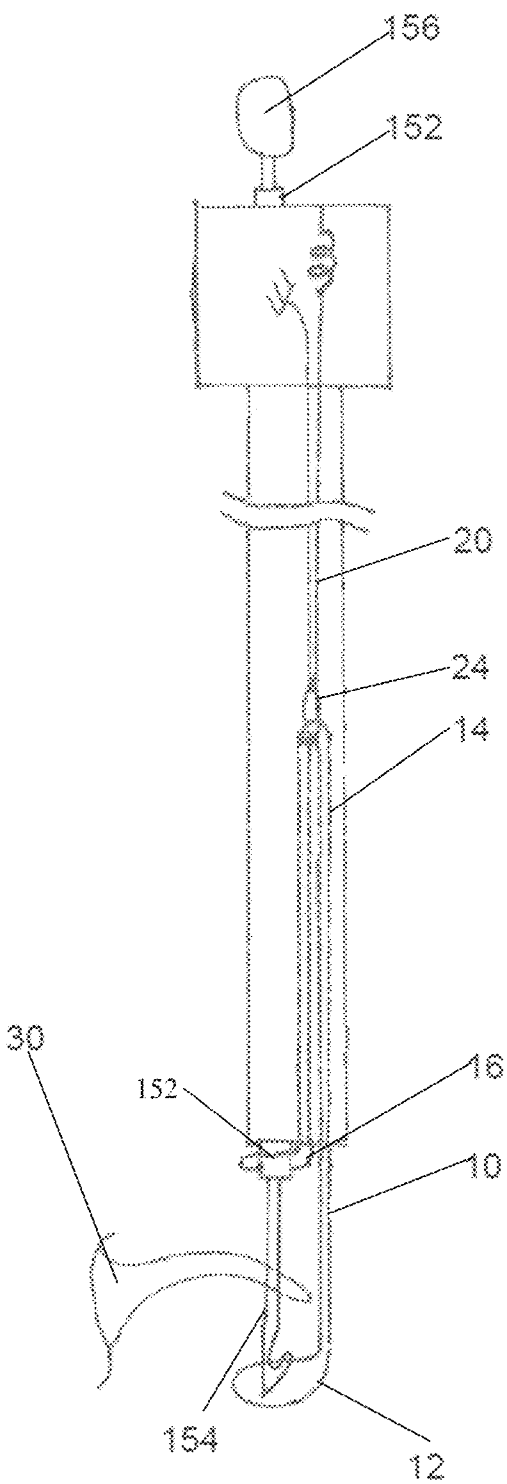


Fig. 5A

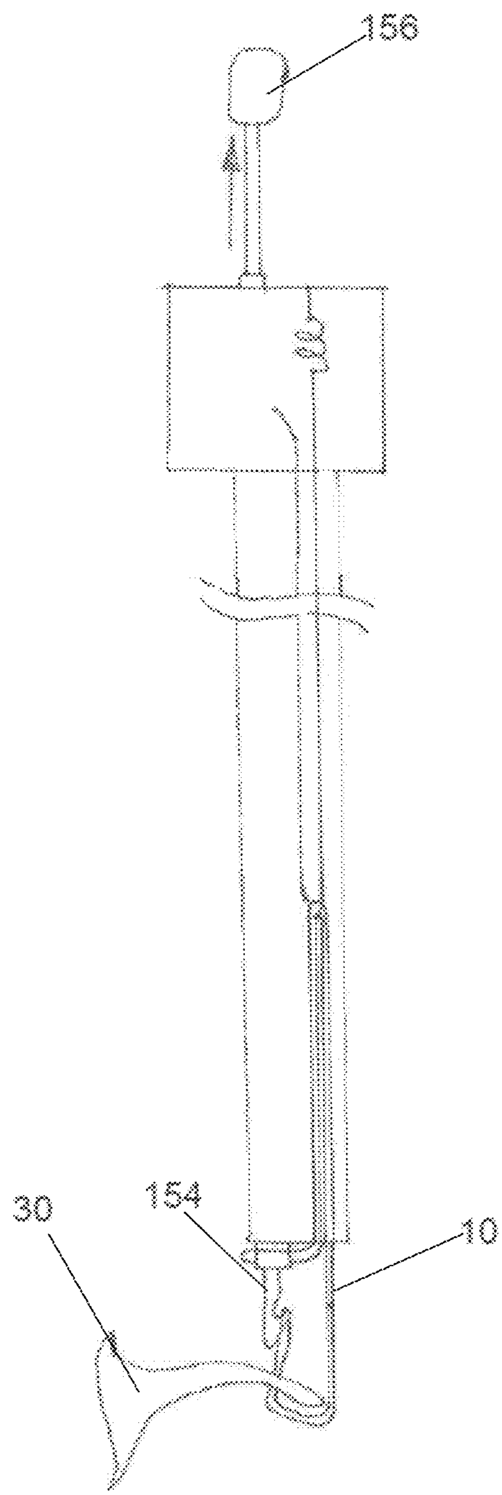


Fig. 5B

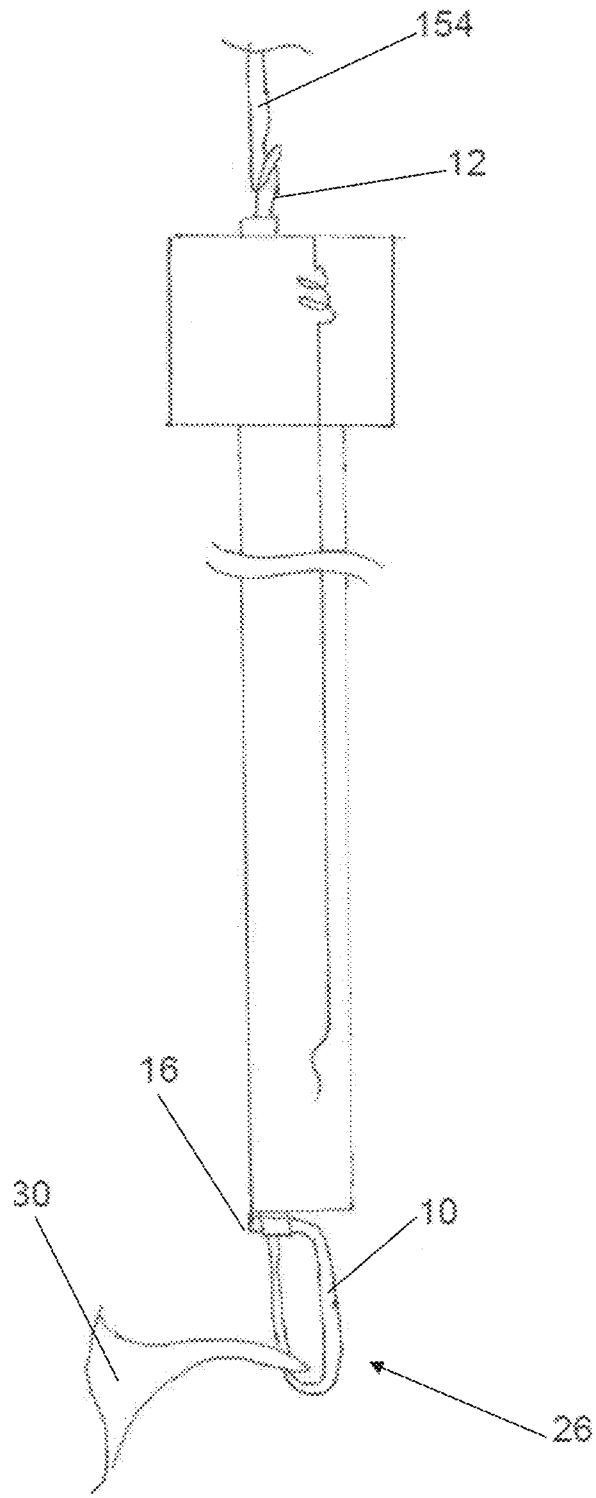


Fig. 5C

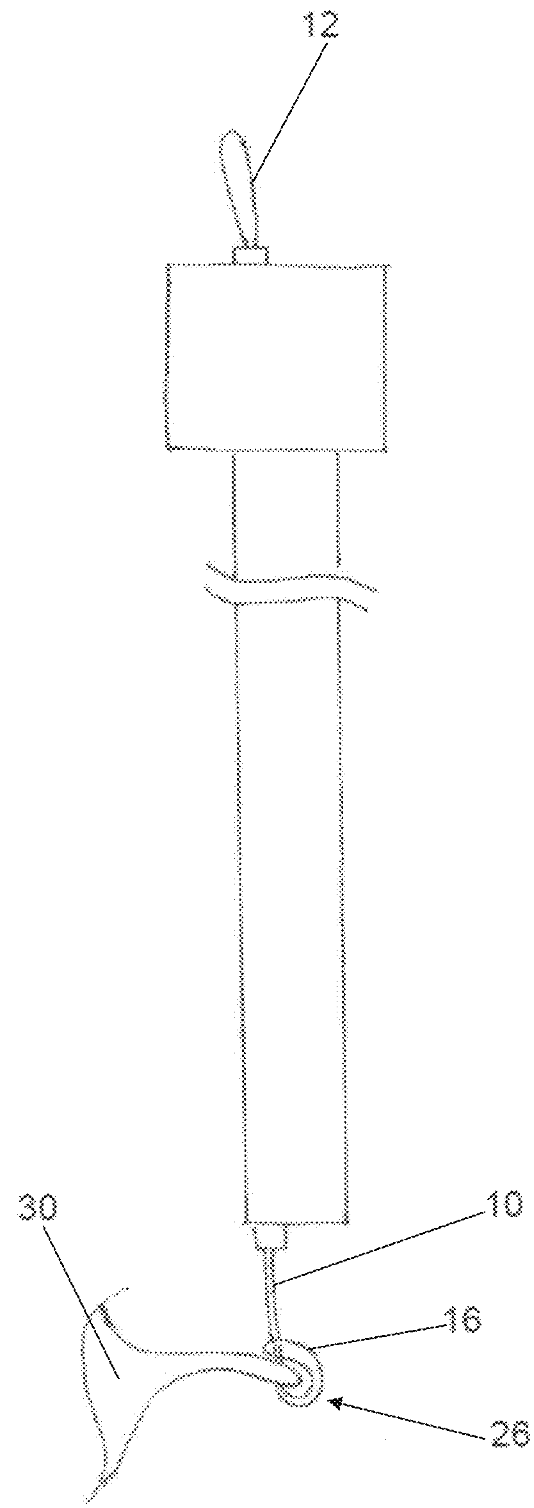
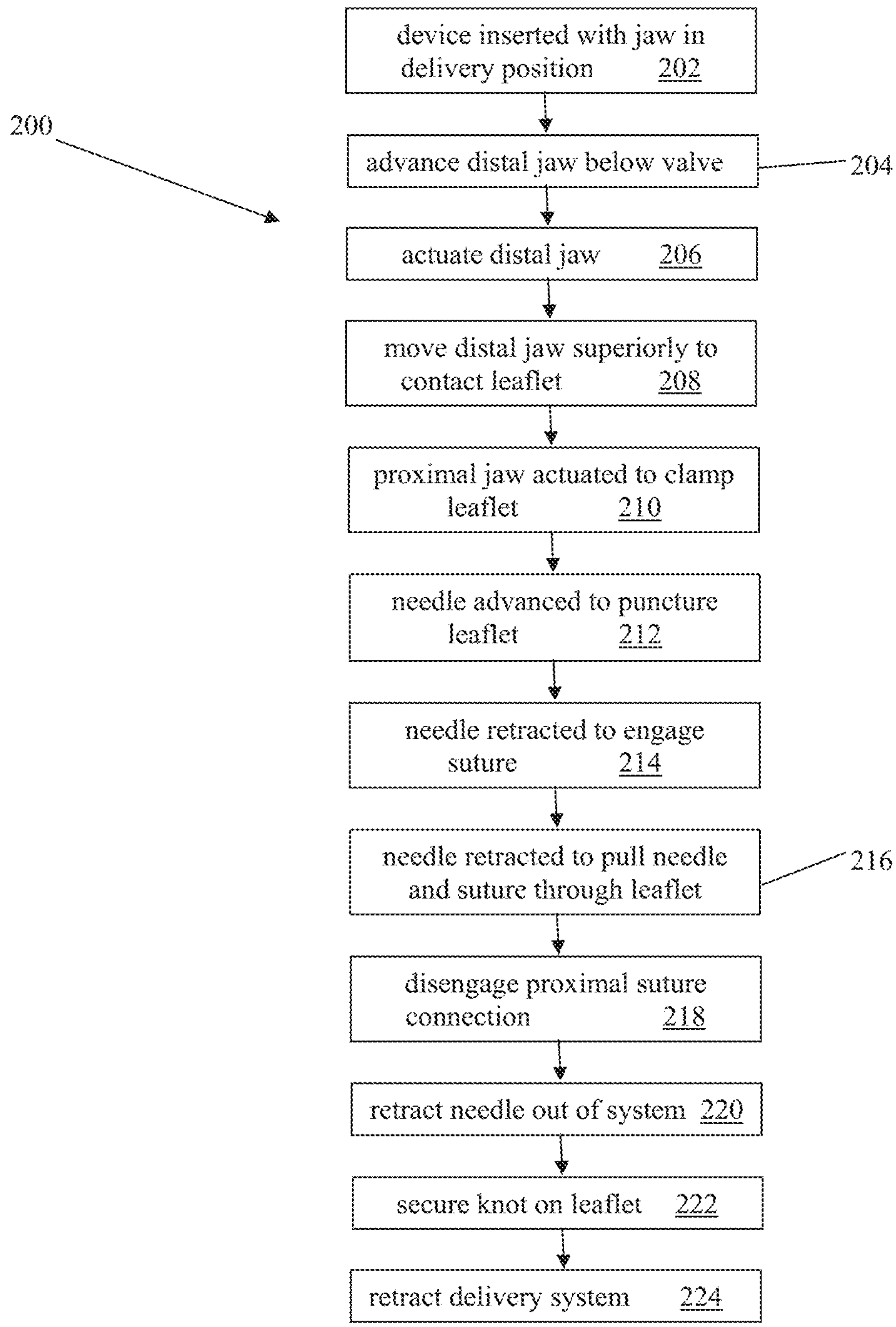


Fig. 5D

Fig. 6


200
device inserted with jaw in delivery position 202
advance distal jaw below valve
204
actuate distal jaw 206
move distal jaw superiorly to contact leaflet 208
proximal jaw actuated to clamp leaflet 210
needle advanced to puncture leaflet 212
needle retracted to engage suture 214
needle retracted to pull needle and suture through leaflet
216
disengage proximal suture connection 218
retract needle out of system 220
secure knot on leaflet 222
retract delivery system 224

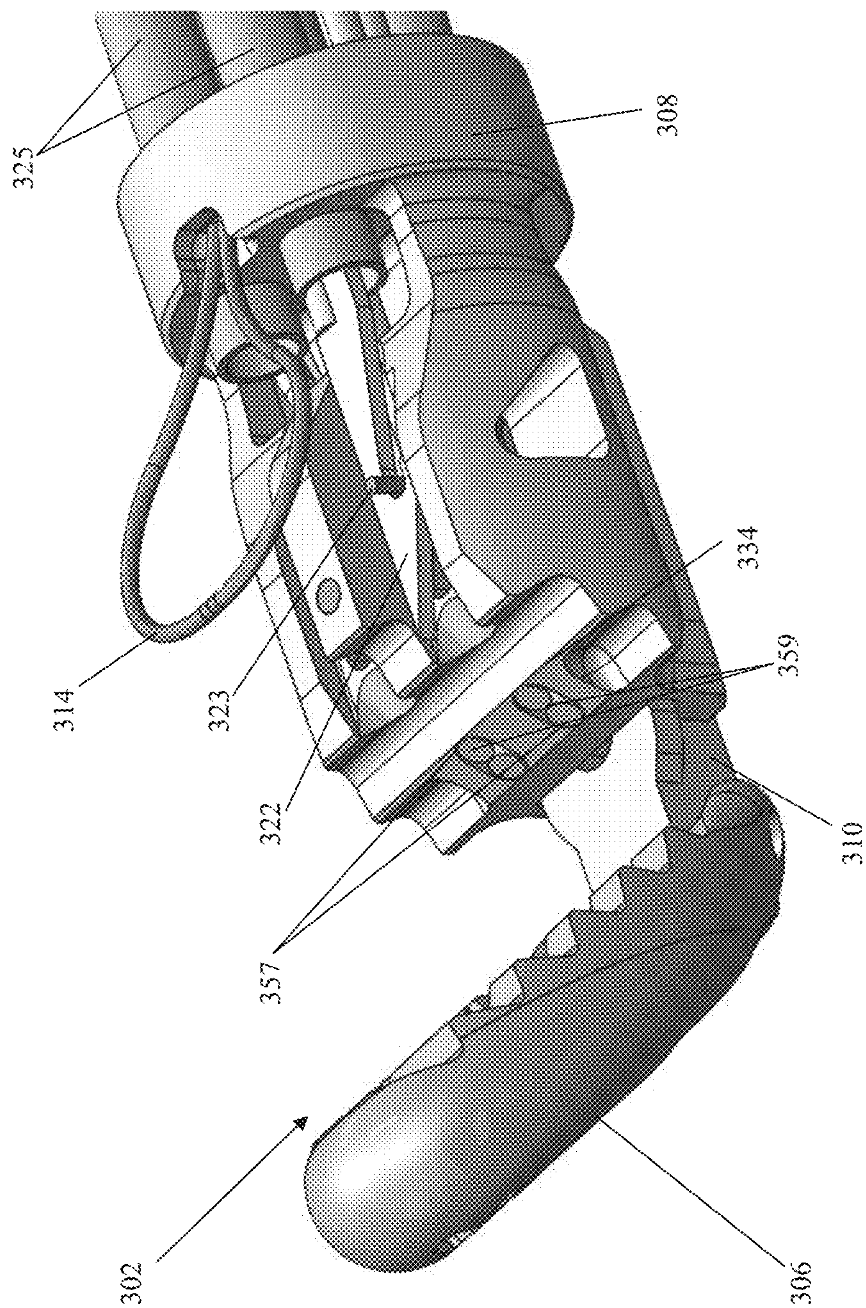


Fig. 7

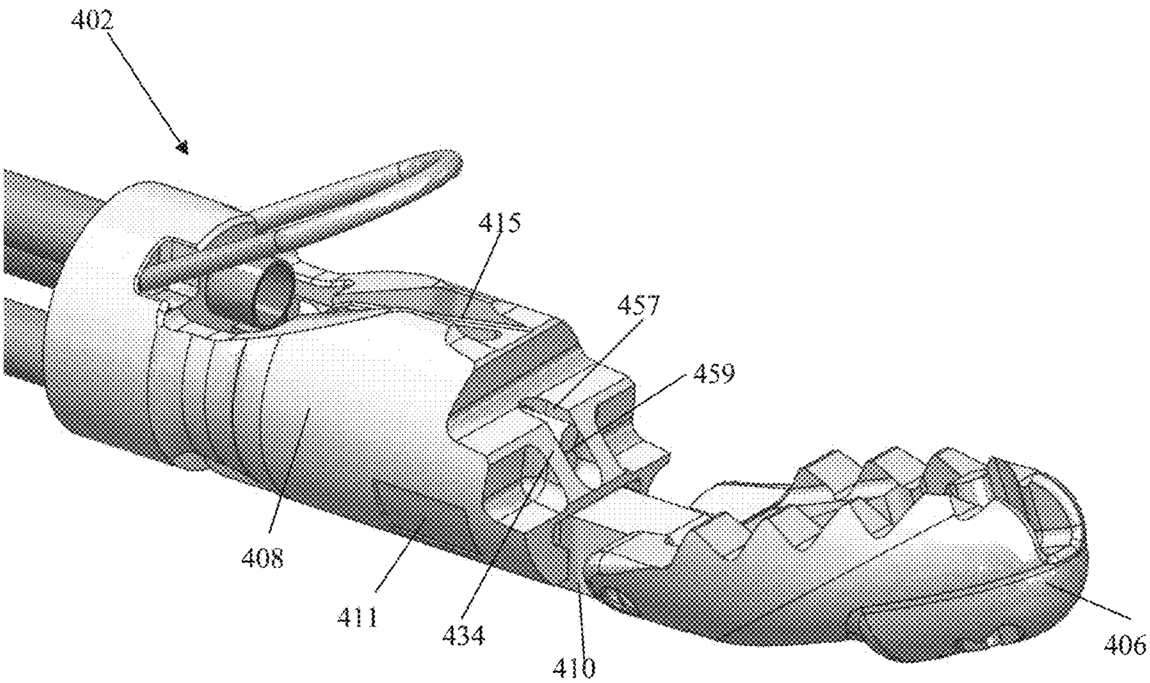


Fig. 8A

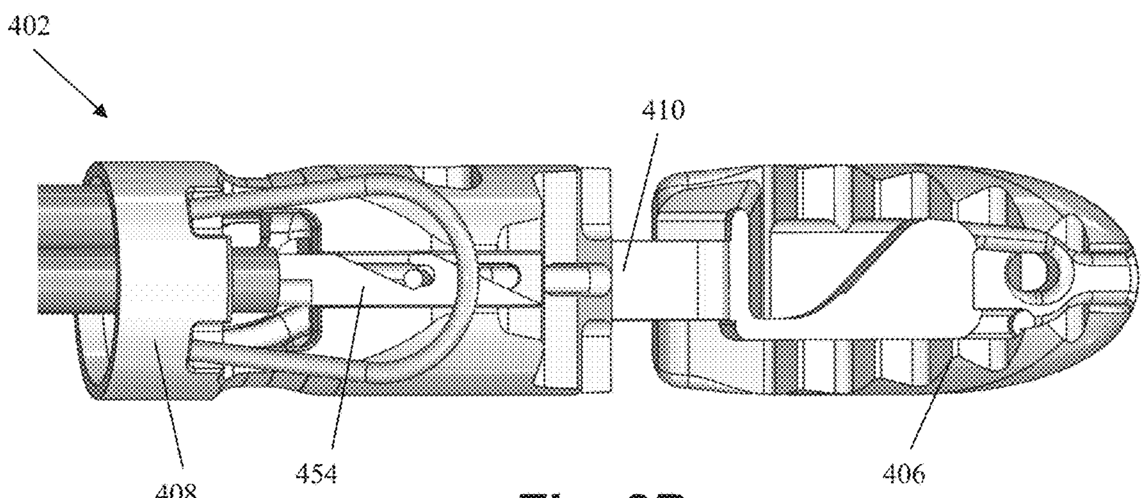


Fig. 8B

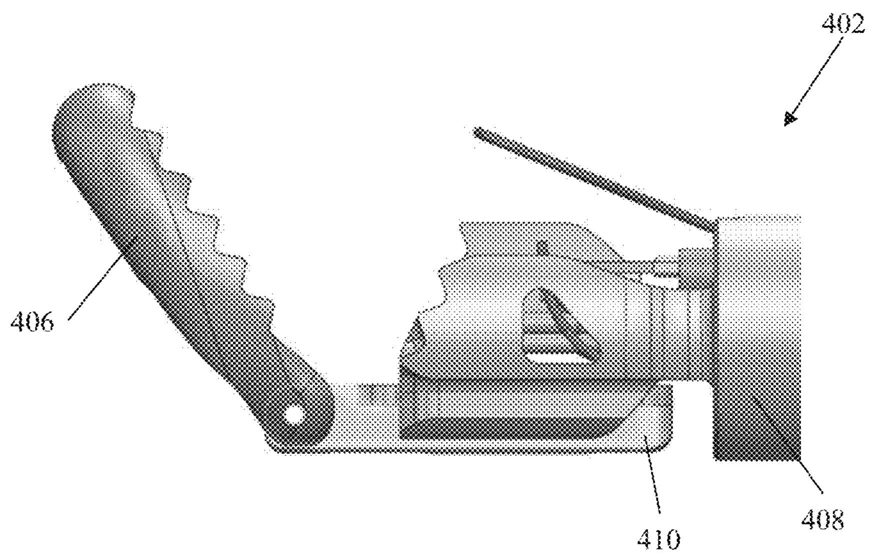


Fig. 8C

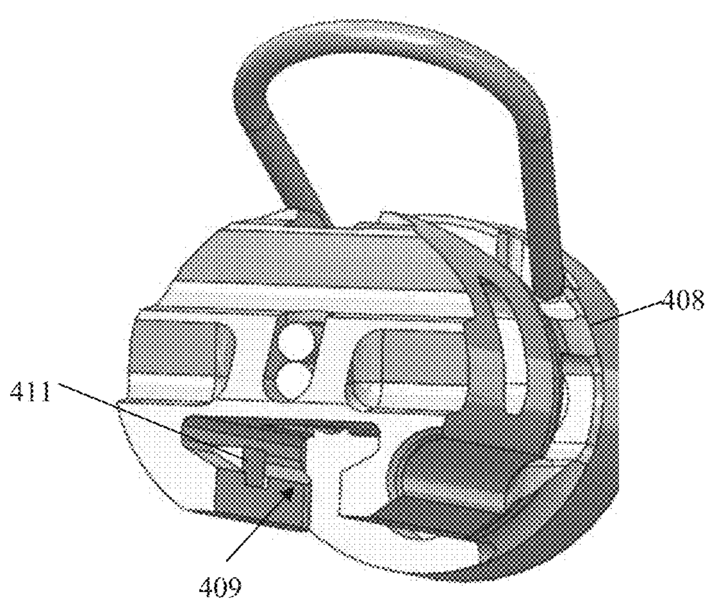


Fig. 8D

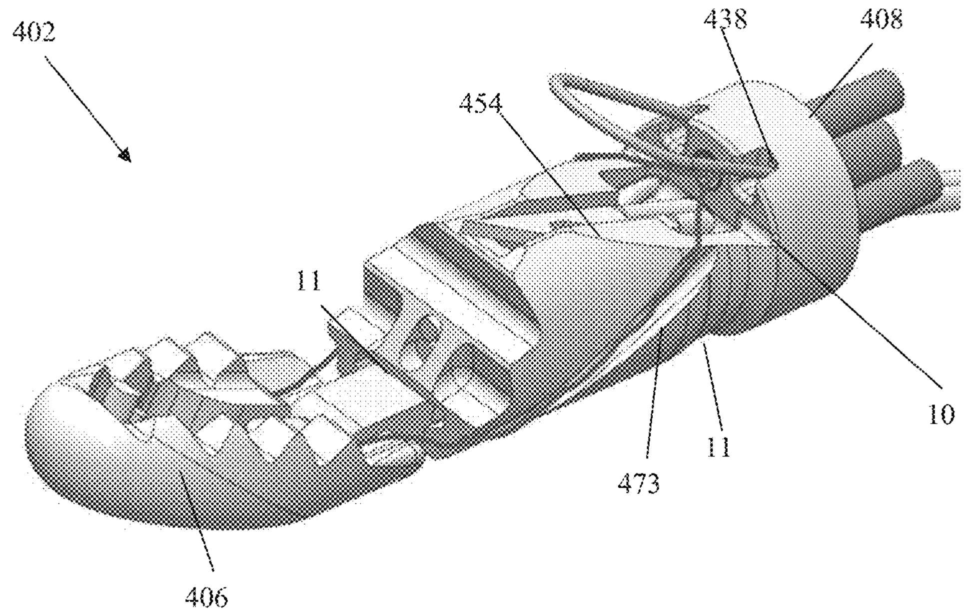


Fig. 9A

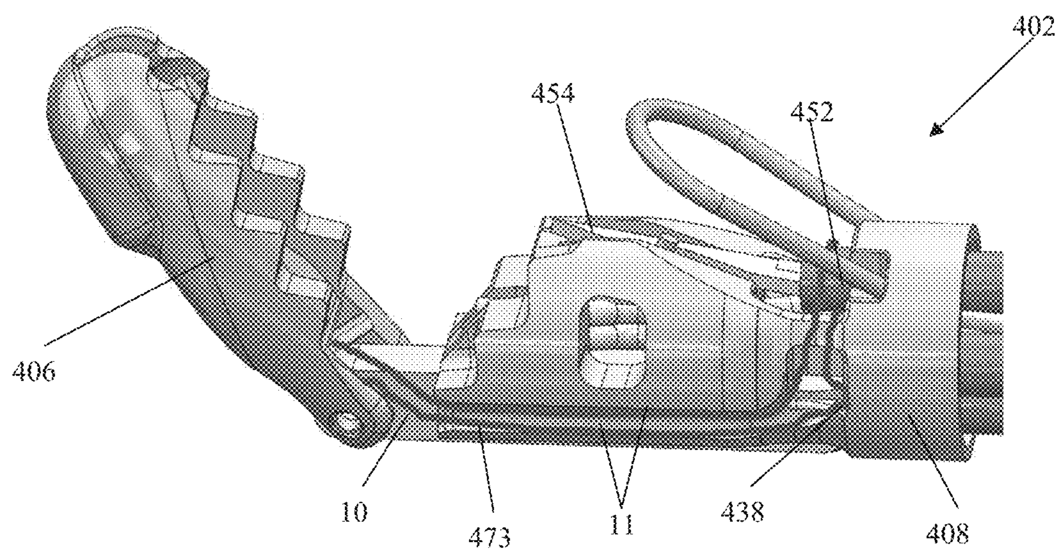


Fig. 9B

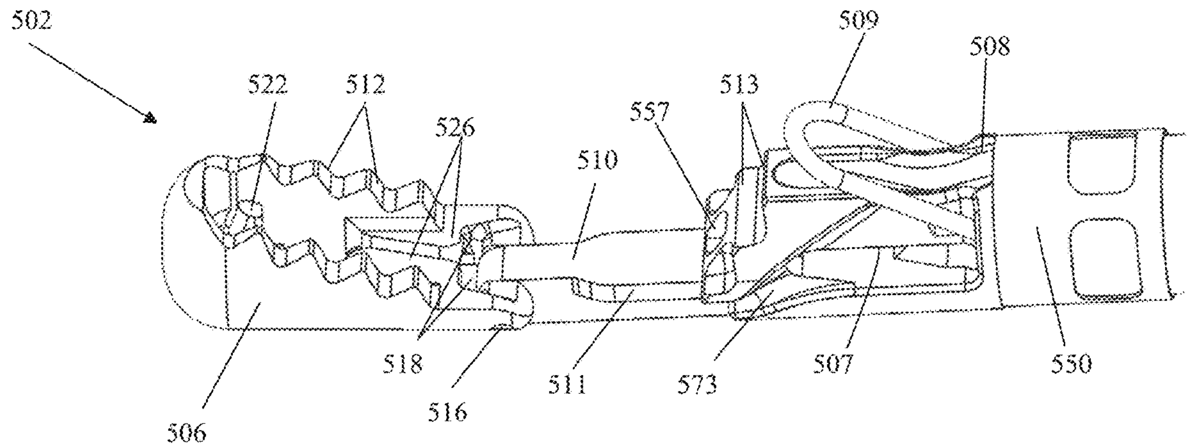


Fig. 10A

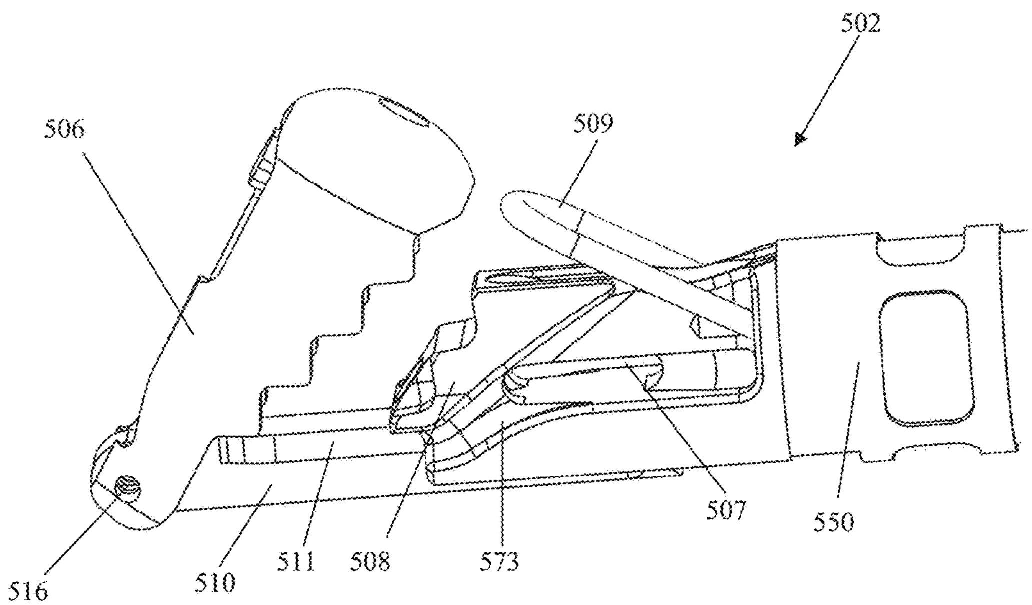


Fig. 10B

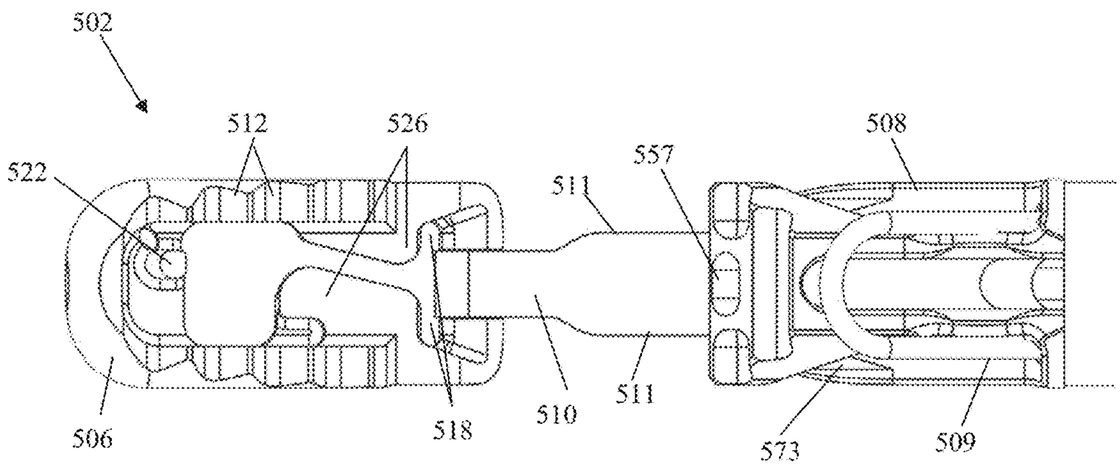


Fig. 10C

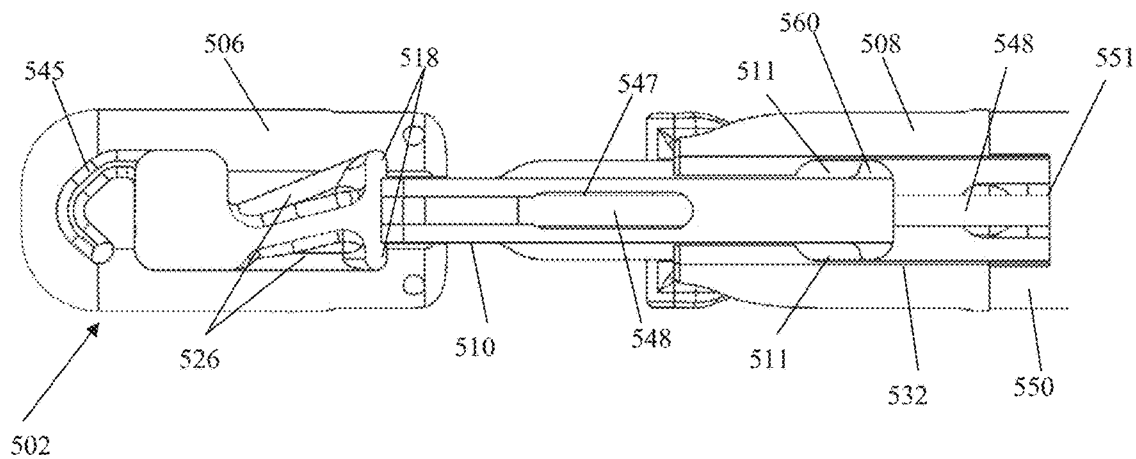


Fig. 10D

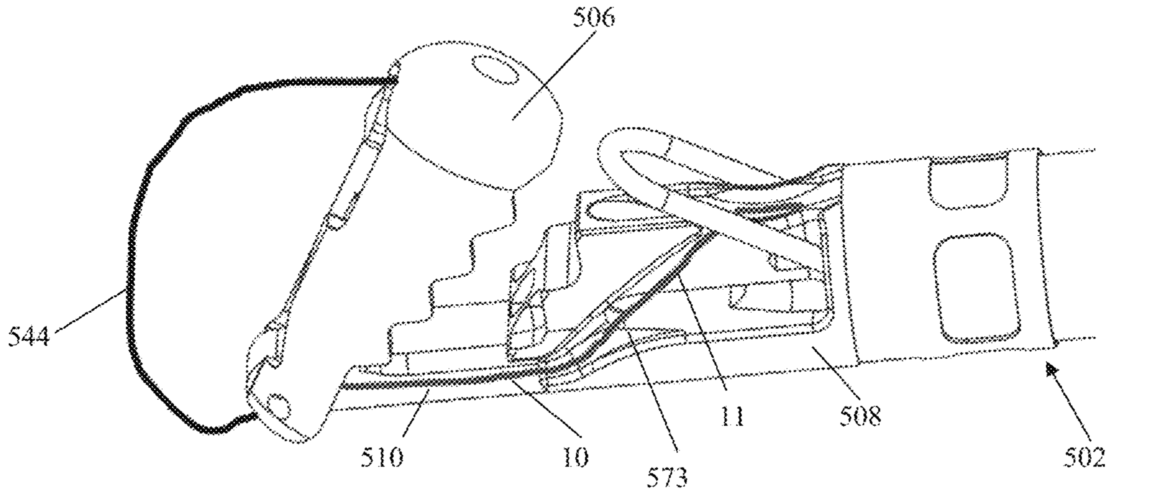


Fig. 11A

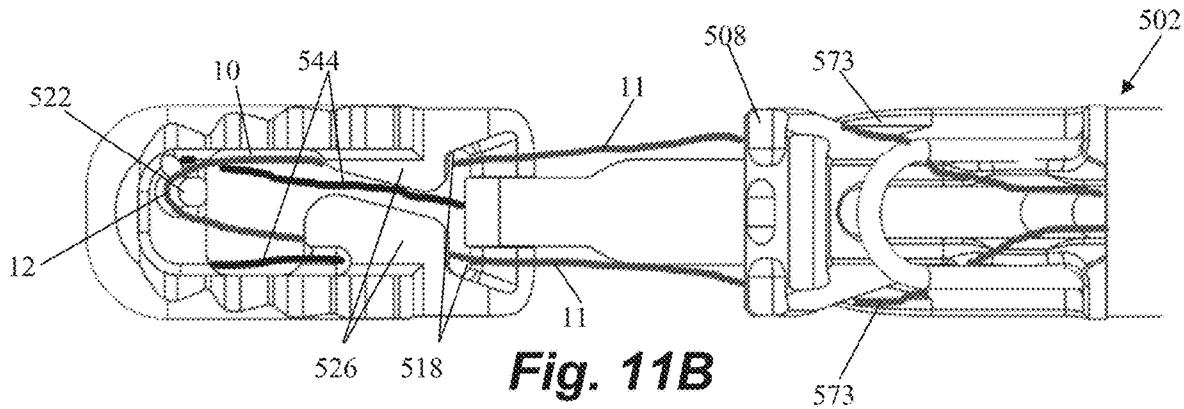


Fig. 11B

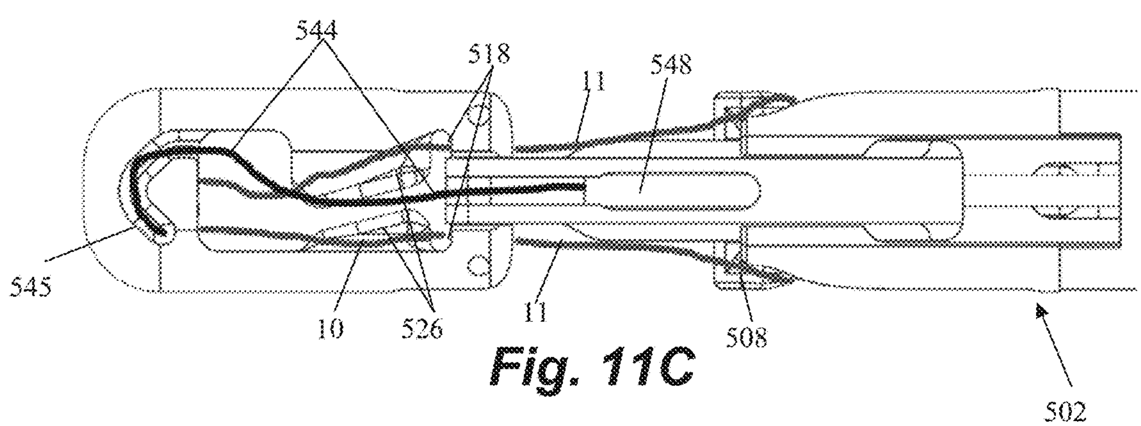


Fig. 11C

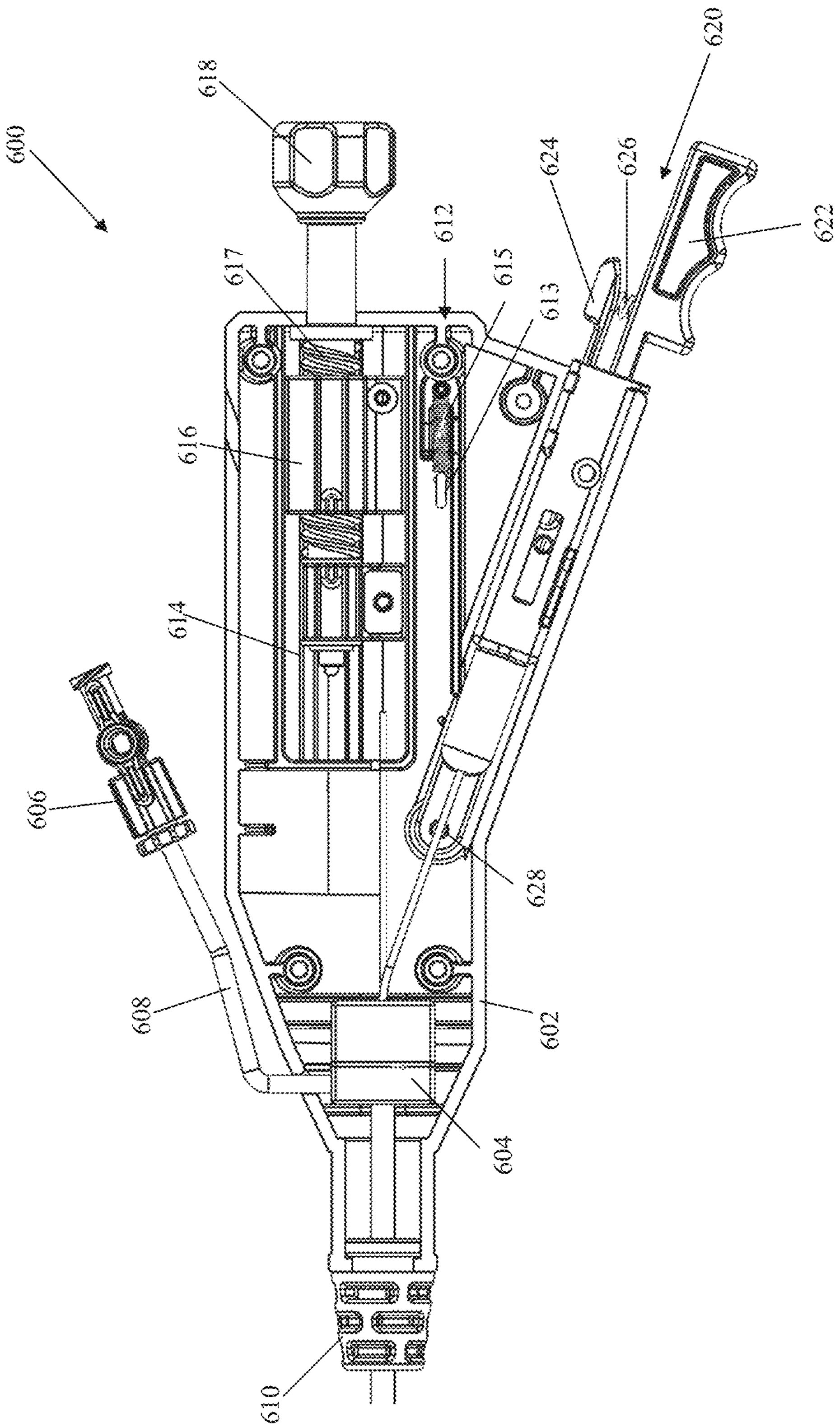

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Fig. 12A

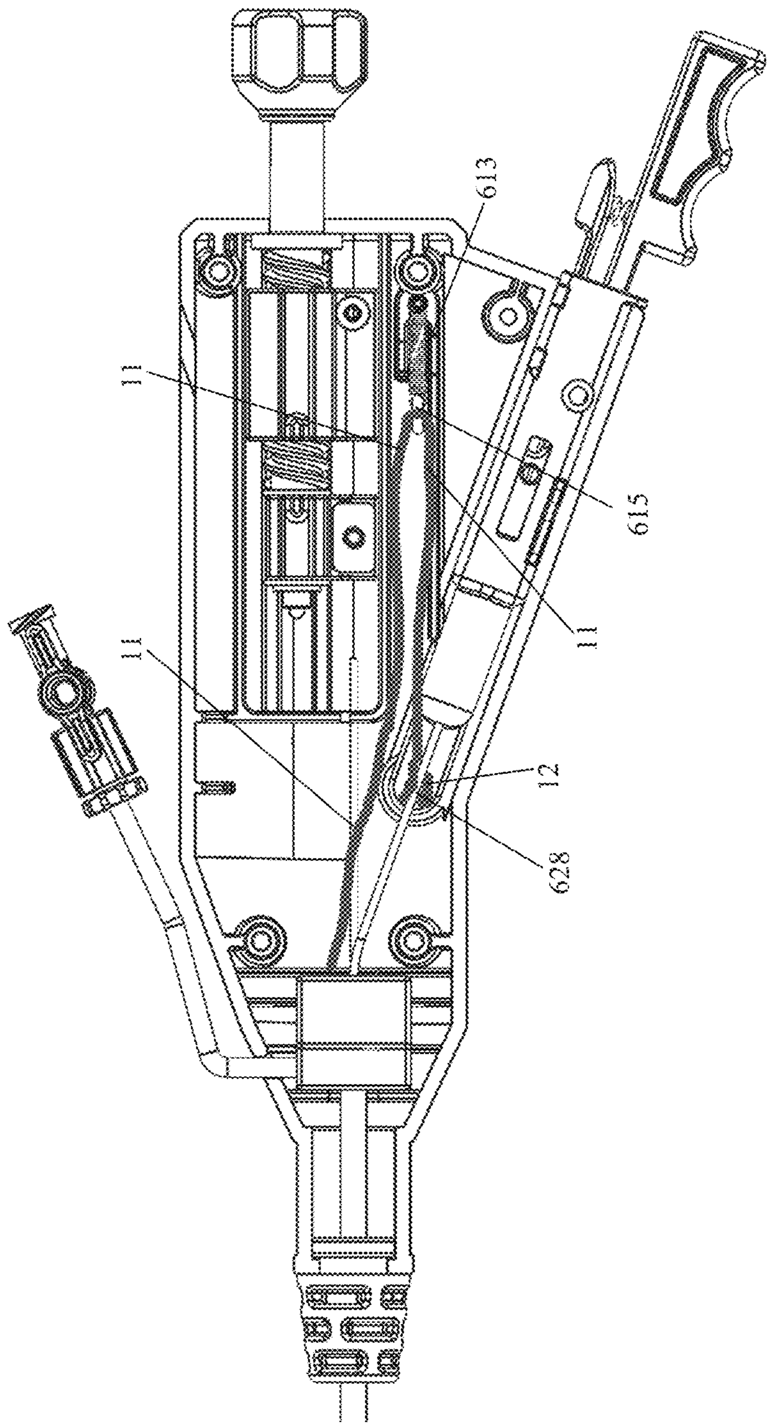

Fig. 12B

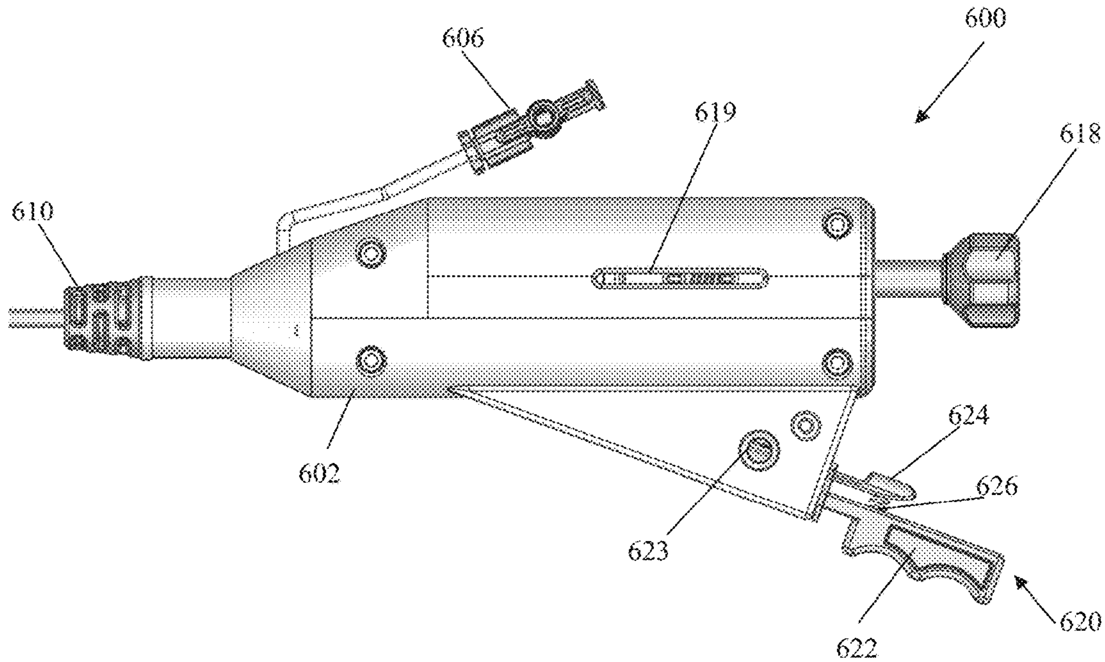

Fig. 12C

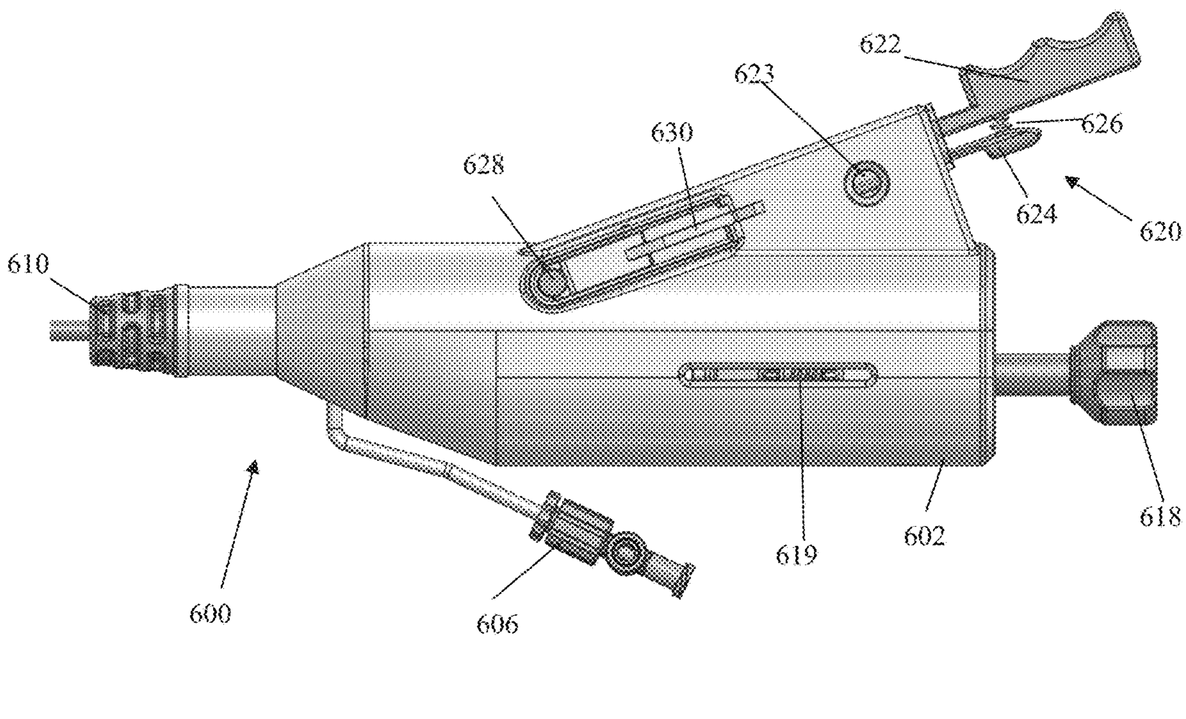

Fig. 12D

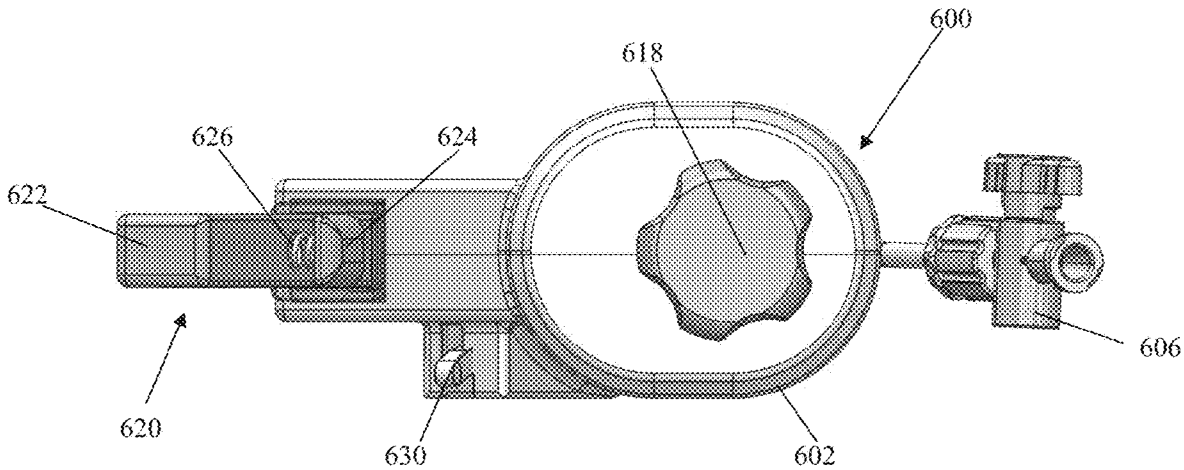

Fig. 12E

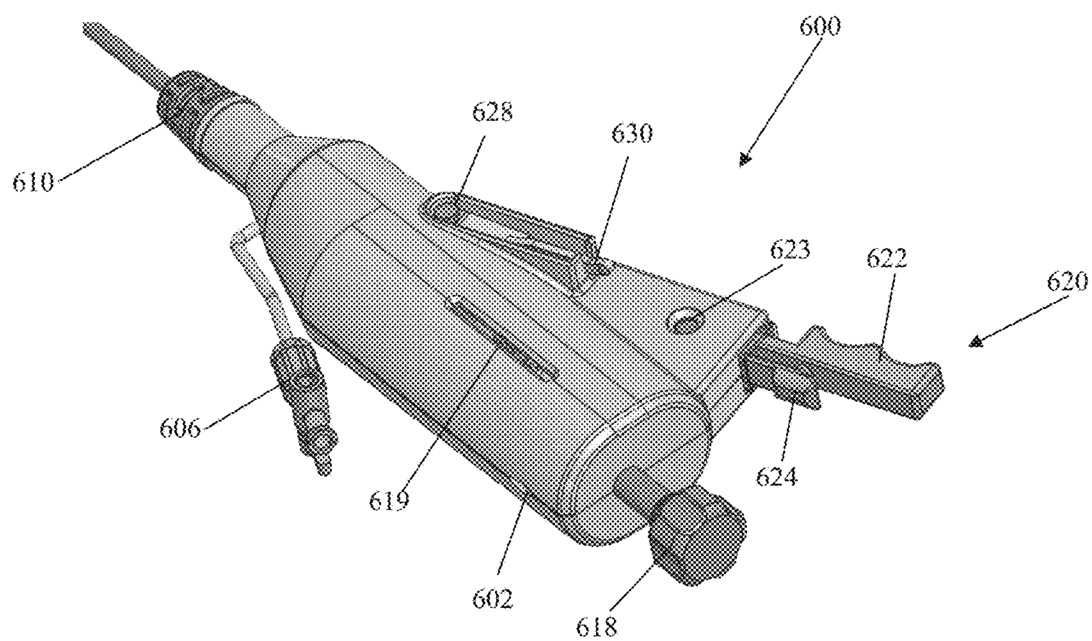

Fig. 12F

DEVICE FOR SUTURE ATTACHMENT FOR MINIMALLY INVASIVE HEART VALVE REPAIR

RELATED APPLICATION

This application claims the benefit of U.S. Provisional Application No. 62/728,349 filed Sep. 7, 2018, which is hereby fully incorporated herein by reference.

TECHNICAL FIELD

The disclosed invention relates to minimally invasive delivery of a suture. More particularly, the disclosed invention relates to attaching the suture as an artificial chordae tendineae to a flailing or prolapsing leaflet in a beating heart.

BACKGROUND

The mitral and tricuspid valves inside the human heart include an orifice (annulus), two (for the mitral) or three (for the tricuspid) leaflets and a subvalvular apparatus. The subvalvular apparatus includes multiple chordae tendineae, which connect the mobile valve leaflets to muscular structures (papillary muscles) inside the ventricles. Rupture or elongation of the chordae tendineae results in partial or generalized leaflet prolapse, which causes mitral (or tricuspid) valve regurgitation. A commonly used technique to surgically correct mitral valve regurgitation is the implantation of artificial chordae (usually 4-0 or 5-0 Gore-Tex sutures) between the prolapsing segment of the valve and the papillary muscle.

This procedure was traditionally an open heart operation generally carried out through a median sternotomy and requiring cardiopulmonary bypass with aortic cross-clamp and cardioplegic arrest of the heart. Using such open heart techniques, the large opening provided by a median sternotomy or right thoracotomy enables the surgeon to see the mitral valve directly through the left atriotomy, and to position his or her hands within the thoracic cavity in close proximity to the exterior of the heart for manipulation of surgical instruments, removal of excised tissue, and/or introduction of an artificial chordae through the atriotomy for attachment within the heart. However, these invasive open heart procedures produce a high degree of trauma, a significant risk of complications, an extended hospital stay, and a painful recovery period for the patient. Moreover, while heart valve surgery produces beneficial results for many patients, numerous others who might benefit from such surgery are unable or unwilling to undergo the trauma and risks of such open heart techniques.

Techniques for minimally invasive thoracoscopic repair of heart valves while the heart is still beating have also been developed. U.S. Pat. No. 8,465,500 to Speziali, which is incorporated by reference herein, discloses a thoracoscopic heart valve repair method and apparatus. Instead of requiring open heart surgery on a stopped heart, the thoracoscopic heart valve repair methods and apparatus taught by Speziali utilize fiber optic technology in conjunction with transesophageal echocardiography (TEE) as a visualization technique during a minimally invasive surgical procedure that can be utilized on a beating heart. More recent versions of these techniques are disclosed in U.S. Pat. Nos. 8,758,393 and 9,192,374 to Zentgraf, which disclose an integrated device that can enter the heart chamber, navigate to the leaflet, capture the leaflet, confirm proper capture, and deliver a suture as part of a mitral valve regurgitation (MR) repair. These minimally invasive repairs are generally performed through a small, between the ribs access point, followed by a puncture into the ventricle through the apex of the heart. Although far less invasive and risky for the patient than an open heart procedure, these thoracoscopic procedures are still involving significant recovery time and pain.

It would be advantageous for a minimally invasive suture delivery system to be able to suture valve leaflets in a beating heart procedure without requiring an open surgical approach or an incision into the exterior ventricular wall of a minimally invasive thoracoscopic approach in order to minimize blood loss and reduce recovery time and pain. For example, various approaches to heart valve repair using intravascular access have been proposed, including U.S. Patent Publication Nos. 2007/0118151 and 2013/0035757 and U.S. Pat. Nos. 7,635,386, 8,043,368 and 8,545,551. These approaches, however, have not resolved various issues with respect to a successful intravascular technique that could match the results of open heart or thorascopic techniques, including the known challenges of effectively grasping and retaining the beating leaflets during a beating heart intravascular procedure.

SUMMARY

Disclosed herein are minimally invasive systems and methods for intravascularly accessing the heart and performing a transcatheter repair of a heart valve by inserting a suture as an artificial chordae into a heart valve leaflet. In various embodiments, such systems and methods can be employed in other heart valve repair procedures such an edge to edge repair to coapt leaflets by inserting one or more sutures that retain the leaflets in a coapted positioned or inserting a suture to repair a tear in a leaflet, for example.

In an embodiment, a suture attachment catheter configured to repair a heart valve by inserting a suture in a valve leaflet of a beating heart of a patient can include a generally flexible catheter body, a suture attachment assembly, and a control handle. The suture attachment assembly can include a proximal clamping jaw, a rail selectively slideable with respect to the proximal clamping jaw and a distal clamping jaw hingedly attached to the distal end of the rail. The control handle can include a rail actuator configured to selectively longitudinally slide the rail with respect to the proximal clamping jaw and a jaw actuator configured to selectively pivot the distal clamping jaw between a first position for delivery of the suture attachment assembly into the heart and a second position for capturing a valve leaflet between the proximal clamping jaw and the distal clamping jaw. In embodiments, a flexible member extends from the jaw actuator through the catheter body to a distal surface of the distal clamping jaw and is selectively moved to pivot the distal clamping jaw.

Various embodiments of systems, devices and methods have been described herein. These embodiments are given only by way of example and are not intended to limit the scope of the present invention. It should be appreciated, moreover, that the various features of the embodiments that have been described may be combined in various ways to produce numerous additional embodiments. Moreover, while various materials, dimensions, shapes, implantation locations, etc. have been described for use with disclosed embodiments, others besides those disclosed may be utilized without exceeding the scope of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention may be more completely understood in consideration of the following detailed description of various embodiments of the invention in connection with the accompanying drawings, in which:

FIGS. **1**A-**1**C depict a distal end of a suture attachment device according to an embodiment.

FIGS. **2**A-**2**B depict a distal jaw of the suture attachment device of FIGS. **1**A-**1**C.

FIG. **3** depicts a proximal clamping jaw of the suture attachment device of FIGS. **1**A-**1**C.

FIGS. **4**A-**4**B depict schematic representations of the routing of one or more sutures through a suture attachment device according to an embodiment.

FIG. **5**A-**5**D depict a sequence of steps for inserting one or more sutures into a valve leaflet according to an embodiment.

FIG. **6** depicts a flowchart of method steps for inserting one or more sutures into a valve leaflet according to an embodiment.

FIG. **7** depicts a distal end of a suture attachment device according to an embodiment.

FIGS. **8**A-**8**D depict a distal end of a suture attachment device according to an embodiment.

FIGS. **9**A-**9**B depict a distal end of a suture attachment device according to an embodiment.

FIGS. **10**A-**10**D depict a distal end of a suture attachment device according to an embodiment.

FIGS. **11**A-**11**C depict a distal end of a suture attachment device according to an embodiment.

FIGS. **12**A-**12**F depict a handle end of a suture attachment device according to an embodiment.

While the invention is amenable to various modifications and alternative forms, specifics thereof have been shown by way of example in the drawings and will be described in detail. It should be understood, however, that the intention is not to limit the invention to the particular embodiments described. On the contrary, the intention is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the invention.

DETAILED DESCRIPTION

The present application describes various devices and methods that can be employed on the beating heart of a patient in a minimally invasive manner to treat mitral valve regurgitation as described above. Embodiments as described herein can be used to restrain a prolapsing leaflet to prevent leaflet prolapse and to promote leaflet coaptation. In other embodiments, such systems and methods can be employed in other heart valve repair procedures such an edge to edge repair to coapt leaflets by inserting one or more sutures that retain the leaflets in a coapted positioned or inserting a suture to repair a tear in a leaflet, for example.

FIGS. **1**A-**1**C depict a distal end **102** of a suture attachment device **100** according to an embodiment. Suture attachment device **100** can be configured as leaflet attachment catheter with the distal end **102** being the distal capture portion of the leaflet attachment catheter. In embodiments, the catheter is configured to enter the patient through a delivery sheath which is inserted at the groin, extends through the inferior vena cava to the right atrium and then through a transeptal puncture into the left atrium. The catheter has a shaft or body **104** of a length to extend through the delivery sheath while allowing the distal end **102** to extend distal to the distal end of the delivery sheath within the patient while also extending proximally to the proximal end of the delivery sheath at the proximal end of the catheter allowing the physician to access the control handle attached to the proximal end of the catheter. In such an embodiment, the catheter body **104** can be flexible.

In embodiments, the total working length of the catheter body can be between about 130 cm and 140 cm. On a typical patient, this length enables the catheter to be advanced into the heart from the groin with additional length for the delivery system catheters and control handles. The catheter can be flexible and configured to be able to flex around a curve having a diameter between 0.75 inches and 1.5 inches, such as, for example, a 0.9 inch diameter curve, depending on the septal puncture location and the specific anatomy of the patient. In other embodiments, the total working length can be between about 100 cm and 170 cm in order to accommodate very short or very tall patients.

In embodiments, the working length of the distal end **102** of the device advanced out of the delivery system can be between about 3 cm and 6 cm. The distal end **102** can be generally rigid, but provided with some flexibility as the device is advanced through the delivery system by a hinged distal jaw as will be described herein. This flexibility enables the distal end to traverse curves on the range of 0.75 inches to 1.5 inches within the internal diameter of the delivery system which, in some embodiments, may be approximately 5-6 mm.

In embodiments, catheter shaft or body is comprised of a combination of stainless steel braid and coil reinforced nylon or polyurethane to provide axial and torsional rigidity along with flexibility. The components of the distal end, such as the clamping jaws as will be described herein, can be comprised of, for example, medical grade polymers or machined stainless steel.

The distal end **102** of the catheter **100** includes a distal jaw **106** and a proximal jaw **108** and mechanisms that actuate the jaws between their respective positions depending on the portion of the procedure being done, as will be described herein. Distal jaw **106** is hingedly attached to a rail **110**. Proximal jaw **108** is selectively slideable along rail **110** and can include a loop **109** configured as a wire extending upwardly therefrom. In embodiments, wire loop **109** can be formed from a shape memory material such as, e.g., nitinol. In operation, distal jaw **106** can selectively be actuated between a first position shown in FIG. **1**A and a second position shown in FIGS. **1**B-**1**C. Proximal jaw **108** can selectively slide along rail **110** between a first, proximal position depicted in FIGS. **1**A-**1**B and second, distal position depicted in FIG. **1**C. In another embodiment, the proximal jaw **108** can be fixed in its axial movement and the rail **110** with the distal jaw **106** attached can slide distally from a first position with respect to the fixed proximal jaw to a second position to effectively increase the distance between the proximal jaw and the distal jaw.

Referring now also to FIG. **2**A-**2**B, further details regarding the distal jaw **106** according to an embodiment will be described. Distal jaw **106** includes a leaflet clamping surface having a plurality of stepped ridges **112** configured to enhance the ability of the jaws to clamp and retain a valve leaflet. Distal jaw **106** further includes a rail opening **114** and a pair of aligned apertures **116** extending through distal jaw **106**. Rail opening **114** is configured to receive a distal end of rail **110** (see FIG. **1**A) with the apertures **116** configured to receive a pin, rod, etc. that extends through a corresponding aperture in rail **110** to form the hinged attachment between distal jaw **106** and rail **110**. Distal jaw **106** further includes a pair of clamping face openings **118**. A portion of clamping face openings **118** extends completely through the distal jaw **106** whereas another portion extends only partway through due to the presence of ledges **120**. A distal post **122** extends upwardly from and a distal aperture **124** extends through each ledge **120**. Clamping face openings **118** further each define a pair of intermediate tabs **126**. A recessed opening **130** also extends through a ledge **128** extending between the openings **118**.

Referring now to FIG. **3**, further details regarding an embodiment of a proximal clamping jaw **108** are depicted. Proximal jaw **108** includes a rail opening **132** that conforms to a shape of the rail **110** (see FIG. **1**A) to enable proximal jaw **108** to selectively slide along rail **110**. Proximal jaw **108** further includes a distal clamping face **134** having a pair of elongate slots **136** therethrough. Elongate slots **136** each define both a suture slot **138** and a needle hole **140**. An actuator aperture **142** is further defined through proximal jaw **108**.

As noted above, and with reference again to FIGS. **1**A-**1**C, distal jaw **106** can be actuated between at least two positions. The first, delivery position is depicted in FIG. **1**A and includes the distal jaw **106** being positioned at an obtuse angle (i.e., an angle between 90 and 180 degrees) relative to the rail **110**. In the depicted embodiment, the distal jaw **106** is positioned approximately 120 degrees relative to the rail. The delivery position is the configuration in which the distal end **102** is delivered through the delivery system to the point of use (i.e., adjacent a valve leaflet). The second, clamping position is depicted in FIGS. **1**B-**1**C and includes the distal jaw **106** positioned at a right angle or acute angle (less than 90 degrees) relative to the rail **110**. In the depicted embodiment, the distal jaw **106** has been actuated approximately 90 degrees relative to the first position, such that the jaw **106** is positioned at an approximately 60 degree angle relative to the rail **110**. The clamping position is the position the distal jaw **106** is moved to when the jaw **106** has been positioned inferior to a leaflet to enable to jaw surface to contact and stabilize the leaflet for capture of the leaflet.

Actuation of the distal jaw **106** between the delivery position and the clamping position is accomplished with a flexible member **144**. In embodiments, flexible member **144** can be a nitinol wire. Flexible member **144** can extend through a lumen **146** through the catheter shaft or body **104** and the rail **110** and exits lumen **146** at a distal face of the rail **110**. The distal end of the flexible member **144** attaches to the distal jaw **106**. Although not depicted as such in FIGS. **1**B-**1**C, in embodiments the flexible member **144** can be attached to the distal jaw **106** via one or more of distal apertures **124**. When this flexible member **144** is further extended from the lumen **146**, its connection to the distal jaw **106** moves the jaw from the first, delivery position in which it is delivered to the second, clamping position in which is able to contact the inferior surface of the valve leaflet. The distal jaw **106** can be moved back to the delivery position by pulling on the flexible member **144**. Flexible member **144** can be controlled with sliding movement of an actuator disposed at a proximal end of the device.

The proximal jaw **108** is actuated with a flexible proximal jaw actuator rod **148**, as shown in FIG. **1**C, that connects to the actuator aperture **142** of the proximal jaw **108**. The actuator rod **148** can be pushed moved an actuator control at the proximal end of the device to advance the proximal jaw **108** along the rail **110** to close the distance between the proximal jaw **108** and the distal jaw **106** to clamp a leaflet therebetween. Wire loop **109** on proximal jaw **108** is configured to approximately mate (on opposite sides of the leaflet) with the distal jaw **106** when both jaws have been actuated to the clamping position. When the proximal jaw **108** is advanced to the actuated distal jaw **106** with the valve leaflet between them, it will provide pressure to stabilize the leaflet between the jaws while minimizing potential damage to the leaflet. In some embodiments, distal clamping face of proximal jaw **108** can be angled to match the angle of distal jaw **106** in the clamping position (i.e., approximately 60 degrees in the depicted embodiment).

The above-described jaw configuration provides a number of advantages. One advantage is that it allows for relatively large surface areas to be included in the clamping portion of the jaw by providing for a first configuration in which the larger distal jaw can more easily be delivered and a second, different configuration in which the larger jaw is employed to capture and retain a leaflet. Another advantage is that the hinged connection reduces the rigid length of the device while still allowing a large jaw opening distance. It does this by allowing the hinged distal jaw to flex as needed while the system is advanced through the small radius that is required for delivery to the mitral valve through the vasculature and a septal puncture.

FIGS. **4**A-**4**B depict schematic representations of an embodiment of a manner in which one or more sutures can be routed through the device **100**. FIG. **4**B depicts device without the proximal jaw **108** and distal jaw **106** as well as a single suture **10** for sake of clarity. FIG. **4**A depicts a pair of sutures **10** carried side by side in device **100**. Because each suture is routed through device in an identical but side by side manner, only the routing of a single suture **10** will be described in detail. In embodiments, one or more sutures can be preinstalled in the catheter prior to delivery to the end user (i.e., surgeon).

Suture **10** can be configured in a continuous loop through device **100**. The routing of the suture **10** through the distal jaw is done by securing a first distal end suture loop **12** portion around the distal post **122** on the leaflet clamping surface side of the distal jaw **106**. The suture **10** then extends from both sides of the post and around the opposite side of the intermediate tabs **126** in the distal clamping jaw **106**, through the suture slots **138** in the proximal jaw **108** and then into a suture channel extending through the catheter body **104**. Within each suture channel of the catheter body **104**, both legs of the suture **10** are doubled with the resulting proximal double loop **14** of suture **10** being held with a separate looped suture **20** which is connected within the proximal control handle **150** by a spring **22** to keep tension on the suture **10** to keep it in place in the catheter body **104**. The second, proximal end suture loop **16** extends from the doubling point **14** distally until it is looped around a needle support tube **152** through which the needle is advanced to penetrate the leaflet and insert the suture around the leaflet.

The proximal control mechanism **150** for the device **100**, depicted schematically in FIG. **4**B, consists of a main body that allows comfortable access to the controls of the device. The separate looped suture **20** is secured in the handle **150** by a spring **22** at one end of the loop **20**, and a disengagable connection **24** at the other. As shown in FIG. **5**A, the needle **154** extends through the control mechanism **150** and the proximal end of the needle contains a handle **156** which allows for comfortable access and control of the needle **154**. The control handle also houses two sliding controls (not depicted). The first sliding control is connected to the distal jaw actuator such as flexible member **144** extending through a lumen in the catheter body **104**. Distal relative movement of the first slider with respect to the control handle **150** will actuate the distal jaw **108**. The second sliding control is connected by a flexible rod **148** extending through the catheter body **104** to the proximal jaw **108**. Distal relative movement of the second slider with respect to the control handle **150** will actuate the proximal jaw **108**. Further details regarding proximal controls for control elements at a distal end of a leaflet capture catheter can be found in U.S. Provisional Patent Application No. 62/647,162, filed Mar. 23, 2018, which is hereby incorporated by reference herein.

In some embodiments, one or more channels through the device could alternatively accommodate or could additionally be added to incorporate fiber optic capture confirmation elements. In such an embodiment, one or more pairs of transmission and return fibers run through the device to enable the capture confirmation system to provide a binary indication of whether the valve leaflet is grasped between the clamping jaws by displaying a first color when a surface of the valve leaflet confronts the fiber optic pairs and a second color (e.g., of blood) when the valve leaflet does not confront the fiber optic pairs at the interior surfaces. Further detail regarding fiber optic capture confirmation of a valve leaflet in a beating heart of a patient can be found in U.S. Pat. Nos. 8,465,500 and 8,758,393 and U.S. patent application Ser. No. 16/363,701, previously incorporated herein by reference.

FIGS. **5**A-**5**D depict a sequence of steps of an embodiment of using device **100** to insert one or more sutures into a valve leaflet and FIG. **6** depicts a flowchart of method steps **200** corresponding to the sequence. FIGS. **5**A-**5**D depict the device **100** without the distal jaw **106** and proximal jaw **108** for sake of clarity. In step **202**, the device is inserted through the delivery system with the distal jaw in the un-actuated, first delivery configuration. In embodiments, access into the heart adjacent the mitral valve can be gained intravascularly as described herein. Further details regarding such access can be found in U.S. Provisional Patent Application No. 62/647,162 incorporated by reference above. In embodiments, the device is inserted with two sutures **10** loaded into the device, though only a single suture **10** is depicted in FIGS. **5**A-**5**D for sake of clarity.

After exiting the delivery system, the distal jaw of the device is advanced below the level of the mitral valve at step **204** and the distal jaw is actuated at step **206** moving the jaw to an angle in which it will contact the valve leaflet. After the device is positioned to the desired point of leaflet attachment, the system is moved superiorly at step **208** with respect to the valve until the lower (distal) jaw contacts the inferior side of the valve leaflet. The proximal jaw is then actuated at step **210** by sliding it along the rail until the leaflet is clamped and stabilized between the jaws.

Once the leaflet **30** is stabilized between the jaws, the needle **154** is advanced at step **212** puncturing the valve leaflet and extended through an opening in the distal jaw and between the suture segments that are positioned around the post and intermediate tabs in the distal jaw. The needle **154** is then retracted which engages the suture with the hook in the needle profile as shown in FIG. **5**A at step **214**. This pulls the distal suture loop **12** off from the distal post of the distal jaw and the needle can then pull the suture loop through the puncture in the valve leaflet **30** at step **216** as depicted in FIG. **5**B. Due to the angle geometry of the intermediate tabs **126**, a distal portion of the suture will remain wrapped around them keeping this distal portion of the suture from contacting the distal side of the leaflet. This enables the suture to be tightened without putting force on the leaflet that could potentially damage the leaflet. With the needle **154** on the proximal side of the valve leaflet **30** and the distal suture loop **12** in the needle hook, the disengagable connection **24** to the proximal suture loop **16** via the separate suture **20** looped around the double loop **14** is released in the control handle at step **218**. Further retraction of the needle **154** at step **220** will then pull the proximal loop **16** distally into the system. At the point that the needle **154** is fully pulled from the system with the distal suture loop **12** that is in the needle **154** exposed, the resulting girth hitch knot **26** is very close to being tightened at the distal end of the system as depicted in FIG. **5**C. The final step **222** to tighten the knot **26** is when the secured distal loop **12** is pulled distally from the needle tube allowing the knot **26** to be secured at the leaflet as depicted in FIG. **5**D.

Once the knot **26** is tightened on the leaflet **30**, the delivery system can be retracted at step **224**. To do so, the proximal jaw may be released and moved proximally, unclamping the valve leaflet. The distal jaw is then unactuated. The change in the distal jaw angle releases the suture from intermediate tabs **126** in the distal jaw which then fully detaches the system from the leaflet. The catheter can then be retracted into the delivery system or the optional second suture may be delivered by moving the system to a different position along the leaflet and repeating the process sequence described above.

Once one or more sutures have been attached to the leaflet, the suture(s) can be adjusted to provide an appropriate length and/or tension for proper valve function and anchored. Further details regarding tensioning and anchoring of sutures can be found in U.S. patent application Ser. Nos. 16/406,736; 16/406,764; and 16/406,799, each of which is hereby incorporated by reference herein.

FIG. **7** depicts another distal end of a leaflet capture catheter **302** according to an embodiment. In this embodiment, the proximal jaw **308** is stationary and longitudinally fixed in place. Rail **310** can be slidable to adjust the distance between proximal jaw **308** and distal jaw **306** to aid in leaflet capture as will be discussed in more detail below with regard to FIGS. **8**A-**8**D. As with leaflet capture catheter **102**, the distal jaw **306** can be pivotable to also aid in leaflet capture. Each needle **322** can include a keying wire **323** that retains the needle in place distally of the needle lumens **325**. In one embodiment, keying wire **323** can be provided with a forward bias and the needle **322** a backward bias to keep the needle in place and when the needle **322** is pushed forward the wire **323** drops out of the path of the needle **322**. In another embodiment, the keying wire **323** can be retracted, such as with a control element on the proximal handle of the device attached to the wire, such that no spring biases are utilized. This embodiment depicts two sets of fiber optic cables **359** (each including one transmission fiber and one return fiber) disposed in fiber optic channels at the distal clamping face **334** of the proximal jaw **108** to aid in verifying proper leaflet capture. The depicted embodiment further includes a stabilizing loop **314** as described in more detail below. Leaflet capture catheter **302** can further include any feature described with respect to the other embodiments disclosed herein.

FIGS. **8**A-**8**D depict another distal end of a leaflet capture catheter **402** according to an embodiment. This embodiment can be configured to carry only a single suture and a single needle **454** and can have a single pair of fiber optics **459** in a fiber optic channel **457**. Distal jaw **406** can be hingedly attached to rail **410**. Rail **410** can be slideable with respect to proximal jaw **408** to adjust a separation distance between the jaws **408**, **410**. Referring to FIGS. **8**C-**8**D, rail **410** can have limited length and be connected to a hypotube (not pictured) controllable from the proximal handle to slide rail **410** within a rail channel **409** defined in proximal clamping jaw **408**. Proximal jaw **408** can further including a locking tab **411** that can mechanically interact with a locking feature on rail **410** to prevent the rail **410** from being completed moved distally from the rail channel **409**. In embodiments, the rail **410** can be biased proximally, towards a closed position with a spring force that is overcome to open the jaws, which enables the jaws to remain clamped around a leaflet once a leaflet is captured. Referring to FIG. **8**A, the needle channel **415** along proximal jaw **408** across which the needle **454** travels to engage the leaflet can be ramped at an upwards angle to ensure the leaflet is pierced sufficiently above the leaflet edge. Leaflet capture catheter **402** can further include any feature described with respect to the other embodiments disclosed herein.

FIGS. **9**A and **9**B depict alternatives as to how a suture can be routed to the distal capture jaw of any of the leaflet capture catheters disclosed herein including, for exemplary purposes, leaflet capture catheter **402**. Referring to FIG. **9**A, in this embodiment the suture **10** extends from a lumen **438** in the proximal clamping jaw **408**, with each strand **11** of the suture extending around a channel **473** one either side of the proximal clamping jaw **408**. The strands then extend up and form a loop at the distal clamping jaw for retrieval by the needle **454**. The suture **10** extends back to the proximal handle control where it can be maintained under an appropriate tension for retrieval by the needle. In this embodiment, the suture lumen **438** is positioned above the needle **454** such that the suture **10** emerges from the proximal clamping jaw **408** from above the needle **454**. Referring now to FIG. **9**B, in this embodiment the suture **10** extends from a lumen **438** in a lower part of the proximal clamping jaw **408** below the needle **454** and wraps around the needle tube **452** containing the needle **454**. Both suture ends **11** then extend along the same channel **473** on a single side of the proximal clamping jaw **408** and to the distal clamping jaw **406**. The suture **10** also can then extend back to the proximal handle control. For suture capture by the needle **454**, the suture **10** is released from the needle tube **452** by an actuation means, such as a control mechanism that attaches to and withdraws the tube or a wire that holds the suture on the tube and is then retracted, for example. In each of these embodiments, the suture **10** can be held in the proximal jaw by a variety of means including, for example, with features such as the distal posts **122** and intermediate tabs **126** described above.

Both of the embodiments of FIGS. **9**A-**9**B greatly simply the suture routing and tensioning aspects of the device with respect to, for example, FIG. **4**B. The suture **10** in these embodiments is no longer folded in half and can extend back to the handle, eliminating the need for the separate looped suture **20** and disengageable connection **24** as well as, in the embodiment of FIG. **9**A, the proximal end suture loop **16** around the needle tube **152**.

FIGS. **10**A-**10**D depict another distal end of a leaflet capture catheter **502** according to an embodiment. Leaflet capture catheter **502** is substantially similar to the leaflet capture catheter **402** described with regard to FIGS. **8**A-**8**D, and any features of either leaflet capture catheter could be utilized with the other. Leaflet capture catheter **502** can further include any features described with respect to the other embodiments disclosed herein. As with previous embodiments, catheter **502** includes a proximal clamping jaw **508** and a distal clamping jaw **506** having an adjustable separation distance via rail **510**.

Distal jaw **506** can be hingedly attached to rail **510** with hinge pin **516** and can be actuated from the open, delivery position (depicted in FIG. **10**A) to the closed, clamping position (depicted in FIG. **10**B) with a flexible member **544** such as that depicted in FIGS. **11**A-**11**C and described above with respect to catheter **102**. For the closed position, the distal jaw **506** can be pivoted to an angle with respect to the rail that generally matches an angle of the proximal jaw **508** as depicted in FIG. **10**B. Distal jaw **506** can include a wire housing **545** having a slot into which the flexible member **544** is inserted and configured to retain the flexible member **544** therein. As will be shown in more detail below, flexible member **544** is routed through the distal jaw **506** and into the wire retainer **545** in such a manner that it is retained in place without any glue or welding required. The distal jaw **506** can be configured to stop pivoting at the depicted capture angle due to the bottom of the jaw abutting the rail, which prevents the jaw from being pivoted too far. Distal jaw **506** can further include suture retention features, including suture routing post **522**, distal suture routing fins **526** and suture routing lumens **518**, which will also be discussed in more detail below. Leaflet grasping teeth **512** can be disposed around a perimeter of distal jaw **506** to aid in retaining a clasped leaflet.

Proximal jaw **508** can similarly include ridged or stepped surfaces **513** that function as leaflet grasping teeth to aid in retaining a leaflet between jaws **506**, **508**. An optics housing **557** can be disposed in proximal jaw **508** to contain fiber optics for confirming leaflet capture. Proximal suture routing fins **573** can be disposed on both sides of proximal jaw **508** to aid in guiding and retaining suture, as described in more detail below. As with previous embodiments, a wire loop **509** can be provided to aid in suture capture and retention by pivoting upwards after the leaflet capture catheter **502** exits the delivery catheter to increase the surface area of the proximal jaw **508** for leaflet capture. The expanded configuration is depicted in FIGS. **10**A-**10**B, in which the wire loop has pivoted up above the proximal jaw. Proximal jaw **508** can be provided with loop cutouts **507** along the sides of jaw to allow the wire loop **509** to be retained along the sides of catheter **502** when in the compressed configuration without increasing the French size of the device.

Rail **510** is slidably extendable from a slot **532** in proximal jaw **508** to adjust the distance of distal jaw **506** from proximal jaw **508**. A rail slide hypotube **548** that extends back to a device handle can be inserted into a slide lumen **547** in rail and fixed to rail by, e.g., soldering, to enable control of movement of rail **510** and distal jaw **506** from the handle. As will be discussed in more detail below, flexible member **144** can extend through slide hypotube **548** between the handle and the wire housing **545** in the distal jaw **506** to enable pivoting control of the distal jaw **506** via flexible member **144** from the handle. Rail **510** can further include rail slide fins **511** that extend outwardly from a body of rail **510**. Rail slide fins **511** extend the full with of the slot **532** to limit the rail **510** to longitudinal or axial movement. Fins **511** are provided with stop features or projections **560** on the proximal end of fins that prevent the rail **510** from being extended completely out of the distal end of the slot **532** of the proximal jaw **508**.

Leaflet capture catheter **502** can further include a jaw attachment hypotube **550** disposed between the catheter body of the device and the proximal jaw component **508**. Jaw attachment hypotube **550** can be a separate hypotube that is, e.g., laser cut, and then reflowed onto the catheter body and laser welded to the proximal jaw to connect the leaflet capture end of the device to the catheter body. Jaw attachment hypotube **550** can further include a proximal rail stop **551** that prevents the rail **510** from moving proximally to a position that would move the distal jaw **506** too close to the proximal jaw **508**.

Referring now to FIGS. **11**A-**11**C, leaflet capture catheter **502** is schematically depicted with a flexible member **544** and a suture **10** routed therethrough. Flexible member **544** extends through and out of rail slide hypotube **548** in rail **510** and then extends around distal jaw **506** and into wire housing **545**. Suture **10** can be configured as a closed loop having a pair of suture ends that extend out of a common opening in the face of proximal jaw **508**, along proximal suture routing fins **573**, underneath the distal portion of proximal jaw **508** and then along each side of the rail **510** towards the distal jaw **506**. Each suture end **11** then extends through one of the suture routing lumens **518** in the distal jaw **506**, beneath one of the suture routing fins **526**, and one end of the suture loop **12** is wrapped around suture routing post **522** under tension for retrieval by needle. Suture routing lumens **518** keep the suture mounted on the distal jaw while the needle is retrieving the suture. When the needle grasps the suture, it pulls the suture off of the suture routing post **522** and back through the leaflet. Suture routing fins **526** keep the suture fixed in the jaw until the suture is completely retrieved by the needle. Once the suture is retrieved, the distal jaw is opened, which releases both the leaflet and the suture from the distal jaw. The suture loop can be formed by tying a knot with the two suture ends. In embodiments, a blood knot can be tied, reinforced with adhesive, and then crimped to reduce the profile. Further details for suture routing and tensioning (generally in the context of a transapical procedure) can be found in U.S. Pat. No. 8,758,393 and https://neochord.com/wpcontent/uploads/2019/02/700010-002_Rev_5_IFU_pc_eng.pdf.

FIGS. **12**A-**12**F depict a handle **600** for controlling a leaflet capture catheter, such as, for example, leaflet capture catheter **502**, according to an embodiment. Although handle **600** will be specifically described for exemplary purposes with regard to control of leaflet capture catheter **502** depicted in FIGS. **10**A-**10**D and **11**A-**11**C, it should be understood that handle **600** could be utilized and/or adapted for use with other leaflet capture catheters, including the other leaflet capture catheters described and depicted herein.

Handle **600** includes a handle body **602** that houses and/or connects to a number of components for controlling leaflet capture catheter and performing a mitral valve repair procedure. A hemostatis hub **604** can be disposed within housing. Hemostatis hub can be a valved structure that prevents blood from leaking back from the catheter into the handle and can also enable air to be flushed from the system through a flush port **606** that connects to hemostasis hub **604** through housing **602** via tubing **608**. Flush port **606** can further enable the device to be flushed with saline to clean out the catheter. A strain relief knob **610** comprised of a flexible material can be disposed at a distal end of handle **600** with catheter body extending therethrough to aid in preventing the catheter body from kinking during the procedure. A suture tensioning assembly **612** can also be disposed within housing **602** to maintain the suture under the tension that keeps the suture positioned at the distal end of the device as described above until captured by the needle. In an embodiment, suture tensioning assembly **612** can include a tensioned spring **613** with an attached o-ring **615** to releasably hold the suture under tension.

Handle **600** further includes a number of control elements that enable an operator to control elements at the distal end of leaflet capture catheter **502** from the proximal portion of the device externally of the body. A rail slide actuation member **614** can be disposed in the housing and connected to the rail slide hypotube **548** such that forward movement of the rail slide actuation member **614** causes the rail slide **510** and distal jaw **506** to move forward and increase a distance between the distal jaw **506** and the proximal jaw **508**. In embodiments, a spring or other resilient element (not pictured) contained in housing can bias the rail slide actuation member **614** and distal jaw **506** to the proximal, closed position. A flexible member actuation nut **616** can be disposed in the housing **602** and affixed to the flexible member **544** such that rotation (e.g., clockwise) of the actuation nut **616** moves the flexible member **544** forward to pivot the distal jaw **506** to the closed position. Reverse rotational movement of the actuation nut **616** (e.g., counter-clockwise) can therefore pull the flexible member **544** back to pivot the distal jaw **506** back to the open position. A control knob **618** can extend distally of the housing **602** for control of both the rail slide actuation member **614** and the flexible member actuation nut **616**. Control knob **618** can be functionally linked to rail slide actuation member **614** and flexible member actuation nut **616** such that pushing or pulling control knob **618** moves the rail slide actuation member **614** (and distal jaw **506**) distally and proximally and rotation of control knob **618** moves the flexible member **544** (thereby opening or closing the distal jaw **506**) such that both functions can be controlled with a single control element. Control knob **618** can include a threaded portion **617** along which actuation nut **616** can travel when control knob **618** is rotated. A slot **619** can be disposed on housing in order to provide an operator with visual confirmation that the distal jaw is opened or closed based on the position of actuation nut **616**.

Handle **600** can further be used to control the needle for puncturing the leaflet and retrieving the suture back through the leaflet. A needle release assembly **620** can include a needle grip **622** and a release handle **624** biased apart by a resilient element such as a spring **626**. Needle release assembly **620** can be functionally connected to the needle such that the needle is prevented from moving forward out of the proximal jaw **608** until the user compresses the needle grip **622** and release handle **624** to overcome the bias of the spring **626**. A needle window **623** can be provided through housing **602** to enable on operator to visually confirm needle deployment. A suture release pin **628** can be disposed within the housing **602** and controlled with a release lever **630** on the housing. Actuation of the release lever **630** removes the suture release pin **628** to free the suture for retrieval and enable remove of the needle handle assembly **620** to retrieve the needle with the suture. In embodiments, the release lever **630** rests on a ledge that prohibits the lever **630** from moving down to release the suture release pin **628** such that the lever must be slid horizontally in order to be moved down in order to prevent accidental release. A needle window **623** can be provided through housing **602** to enable on operator to visually confirm needle deployment prior to releasing the suture.

FIG. **12**B depicts the routing of a suture **10** through the handle **600** according to an embodiment. The suture loop **12** exits through the hemostatis hub **604** and wraps around the o-ring **615** attached to the tensioning spring **613** of the suture tensioning assembly **612**. The end of the suture loop **12** is placed over the suture release pin **628** to enable the suture to be retrieved from the distal jaw **506** upon actuation of the release button **620**.

Although specifically described with respect to the mitral valve, it should be understood the devices described herein could be used to treat any other malfunctioning valve, such as the tricuspid and aortic valves. Further, although it should be understood that the devices described in the present application could be implanted into the beating heart of the patient via various access approaches known in the art, including transapical approaches (e.g., through the apex of the left ventricle) and transvascular approaches, such as transfemorally (through the femoral vein). One example of a transapical access approach that could be employed is described in U.S. Pat. No. 9,044,221, previously incorporated by reference herein. One example of a transvascular access approach that could be employed is described in U.S. Patent Publication No. 2013/0035757, which is hereby incorporated by reference herein. This versatility in access approach enables the access site for the procedure to be tailored to the needs of the patient.

Various embodiments of systems, devices, and methods have been described herein. These embodiments are given only by way of example and are not intended to limit the scope of the present invention. It should be appreciated, moreover, that the various features of the embodiments that have been described may be combined in various ways to produce numerous additional embodiments. Moreover, while various materials, dimensions, shapes, implantation locations, etc. have been described for use with disclosed embodiments, others besides those disclosed may be utilized without exceeding the scope of the invention.

Persons of ordinary skill in the relevant arts will recognize that the subject matter hereof may comprise fewer features than illustrated in any individual embodiment described above. The embodiments described herein are not meant to be an exhaustive presentation of the ways in which the various features of the subject matter hereof may be combined. Accordingly, the embodiments are not mutually exclusive combinations of features; rather, the various embodiments can comprise a combination of different individual features selected from different individual embodiments, as understood by persons of ordinary skill in the art. Moreover, elements described with respect to one embodiment can be implemented in other embodiments even when not described in such embodiments unless otherwise noted.

Although a dependent claim may refer in the claims to a specific combination with one or more other claims, other embodiments can also include a combination of the dependent claim with the subject matter of each other dependent claim or a combination of one or more features with other dependent or independent claims. Such combinations are proposed herein unless it is stated that a specific combination is not intended.

For purposes of interpreting the claims, it is expressly intended that the provisions of 35 U.S.C. § 112(f) are not to be invoked unless the specific terms "means for" or "step for" are recited in a claim.

Any incorporation by reference of documents above is limited such that no subject matter is incorporated that is contrary to the explicit disclosure herein. Any incorporation by reference of documents above is further limited such that no claims included in the documents are incorporated by reference herein. Any incorporation by reference of documents above is yet further limited such that any definitions provided in the documents are not incorporated by reference herein unless expressly included herein.

The invention claimed is:

1. A suture attachment catheter configured to repair a heart valve by inserting a suture in a valve leaflet of a beating heart of a patient, comprising:

- a generally flexible catheter body having a proximal end, a distal end and a length greater than 100 cm;
- a suture attachment assembly proximate the distal end of the catheter body, the suture attachment assembly including:
  - a proximal clamping jaw disposed adjacent the distal end of the catheter body;
  - a rail having a proximal portion and distal portion, the proximal portion configured to be selectively longitudinally slideable with respect to the proximal clamping jaw; and
  - a distal clamping jaw hingedly attached to the distal portion of the rail;
- a control handle operable attached to the proximal end of the catheter body, the control handle including:
  - a rail actuator configured to selectively longitudinally slide the rail with respect to the proximal clamping jaw; and
  - a jaw actuator configured to selectively pivot the distal clamping jaw between a first position for delivery of the suture attachment assembly into the heart and a second position for capturing a valve leaflet between the proximal clamping jaw and the distal clamping jaw; and
- a flexible member extending from the jaw actuator through the catheter body to a distal surface of the distal clamping jaw, wherein the jaw actuator selectively moves the flexible member to pivot the distal clamping jaw.

2. The suture attachment catheter of claim **1**, further comprising a control knob at the control handle, wherein the control knob is configured to control both the rail actuator and the jaw actuator.

3. The suture attachment catheter of claim **2**, wherein the control knob is configured to moved longitudinally to control the rail actuator and to be rotated to control the jaw actuator.

4. The suture attachment catheter of claim **1**, wherein the flexible member extends into a housing in the distal clamping jaw.

5. The suture attachment catheter of claim **1**, wherein the flexible member comprises a wire.

6. The suture attachment catheter of claim **1**, further comprising a wire loop extending from the proximal clamping jaw, the wire loop configured to effectively increase a capture area of the proximal clamping jaw.

7. The suture attachment catheter of claim **6**, wherein the wire loop is configured to automatically transition from a collapsed position to an expanded position when the proximal clamping jaw is extended out of a delivery catheter in the heart.

8. The suture attachment catheter of claim **1**, wherein the distal clamping jaw includes a suture routing post configured to retain a suture thereon under tension.

9. The suture attachment catheter of claim **1**, wherein a perimeter of the distal clamping jaw defines a plurality of stepped teeth configured to enhance retention of the leaflet between the distal clamping jaw and the proximal clamping jaw.

10. The suture attachment catheter of claim **9**, wherein the proximal clamping jaw defines a plurality of stepped teeth configured to enhance retention of the leaflet between the distal clamping jaw and the proximal clamping jaw.

11. The suture attachment catheter of claim **1**, further comprising one or more fiber optic cables extending from the control handle to the proximal clamping jaw, and wherein the proximal clamping jaw includes an opening on a clamping face of the proximal clamping jaw to enable the one or more fiber optic cables to confirm capture of a valve leaflet between the proximal clamping jaw and the distal clamping jaw.

12. The suture attachment catheter of claim **1**, further comprising a needle selectively slideable within the catheter body, the needle configured to be extended from the proximal clamping jaw to penetrate a valve leaflet to insert a suture through the valve leaflet when the valve leaflet is captured between the proximal clamping jaw and the distal clamping jaw.

13. The suture attachment catheter of claim **12**, further comprising a needle release disposed at the control handle, and wherein the needle is prevented from extending from the proximal clamping jaw until the needle release is actuated.

14. The suture attachment catheter of claim **12**, further comprising a suture configured to be retained on the distal clamping jaw for retrieval by the needle and a suture tensioning assembly disposed at the control handle, the suture tensioning assembly configured to apply tension on the suture to enable the suture to be retained on the distal clamping jaw under tension.

15. The suture attachment catheter of claim **14**, further comprising a suture release pin disposed in the handle, the suture release pin configured to release the tension on the suture to enable the suture to be retrieved from the distal clamping jaw.

16. The suture attachment catheter of claim **1**, wherein the suture attachment assembly is less flexible than the catheter body.

17. The suture attachment catheter of claim **1**, wherein the suture attachment catheter is configured for insertion into a left atrium of the patient's heart via a vascular access to a right atrium of the heart and a transseptal access between the right atrium and the left atrium.

18. The suture attachment catheter of claim **1**, wherein the rail is configured to slide in a channel of the proximal clamping jaw.

19. The suture attachment catheter of claim **18**, further comprising a distal rail lock configured to prevent the rail from being slid distally beyond the proximal clamping jaw.

20. The suture attachment catheter of claim **1**, further comprising a proximal rail lock configured to prevent the rail from being slid proximally to bring the distal clamping jaw closer than a predetermined minimum distance from the proximal clamping jaw.

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